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Biotechnology in the San Francisco Bay Area

A Report of the Association of Bay Area Governments

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A Report of the Association of Bay Area Governments

September 1988

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Acknowledgements

Task Force Members

Tom Hsieh, Chair	Supervisor, City and County of San Francisco
Selina Bendix	President, Bendix Environmental Research, Inc.
Edward Blakely	Chair, Dept. of City & Regional Planning, University of California, Berkeley
Martha Bowden	Product Manager, Hewlett Packard
Brook Byers	Partner, Kleiner, Perkins, Caufield, & Byers
Ronald Cowan	Chairman, Doric Development/Harbor Bay
Robert Gorlow	Investment Manager, Prudential Development Group
Zane Gresham	Partner, Morrison & Forester
Mary Griffin	Supervisor, San Mateo County
Bill Higgins	Vice President, Genentech, Inc.
Richard Love	President, Triton Biosciences, Inc.
Richard Morten	Planning Director, S.F. Chamber of Commerce
Michelle Perrault	Immediate Past President, National Sierra Club
Tom Powers	Supervisor, Contra Costa County
David Ramsay	Senior Vice Chancellor, University of California, San Francisco
Niels Reimers	Director, Technology Licensing, Stanford University
Joseph Sax	Professor, Boalt School of Law, University of California, Berkeley
Dick Spees, ABAG President	Councilmember, City of Oakland
Charles Webster	Merritt Peralta Medical Center

Note: While the members are affiliated with the above organizations, as Task Force members they acted as individuals

Principal Research Staff

Economic Analysis of Bioindustry

Raymond Brady	Research Director
Sandra Rivera	Intern

University Research

Chin Ming Yang	Senior Research Analyst

Regulatory Framework

Gary Binger	Planning Director
Maria Rea	Intern

Findings and Recommendations

Patricia Perry	Senior Planner

Agency Management

Revan A.F. Tranter	Executive Director
Eugene Y. Leong	Deputy Executive Director

Project Management

Gary Binger	Planning Director
Patricia Perry	Editor

Technical Assistance

Yim Lam	Programmer
Barbara Sarao	Secretary

ABAG Association of Bay Area Governments
P.O. Box 2050
Oakland, California 94604-2050

(415) 464-7900
8th and Oak Streets
Oakland, California

Biotechnology...

the application of biological
systems and organisms to
technical and industrial processes

Table of Contents

Acknowledgements iii
Introduction ix
Executive Summary x

Chapter 1 Task Force Formation and History

History 1-2
Formation 1-2
Membership 1-3
Meetings 1-3
Work Program 1-3
Public Forums 1-6

Chapter 2 Task Force Findings

Bay Area Leading Bioscience Center 2-3
Bioindustry Contribution to Bay Area Economy 2-3
Synergy Between Bioindustry and Universities 2-4
Regulation and Public Acceptance 2-5
Need for Training for Bioindustry Workers 2-7
Communicating With Elected Officials and the Media 2-8
Maintaining the Bay Area as a Bioscience Center 2-9

Chapter 3 Task Force Recommendations

Public Education and Promotion 3-2
Workshops 3-2
Center for Biosciences 3-3
Bioscience Resource Clearinghouse 3-3

Regulatory Issues 3-3
Research Institutions and Bioscience Companies 3-4
Local Government 3-4
Regional Agencies 3-6
State and Federal Agencies 3-6

Animal Use in Research 3-7

Chapter 4 Bay Area Bioindustry: Structure, Constraints, and Potential

Summary 4- 3
Introduction 4- 4
Overview: Bay Area Bioindustry 4- 5
Industry Classification 4- 7
Changing Organizational Base 4- 9
Research Concentration of Biotechnology Firms 4-12
Product Development Links to Multi-National Firms 4-15
Location within the Bay Area 4-17
Local Economic Impacts 4-19
Public Policy Implications and Growth Potential 4-22
Recommendations 4-24
Conclusions 4-25
Afterword 4-25
Footnotes 4-26
References 4-27

Appendices - Bay Area Bioindustry Firms
A Names and Locations 4-A-1
B Description and Year Founded 4-B-1
C History and Financial Status 4-C-1
D Employment and Operating Statistics 4-D-1
E Links to Multi-National Firms 4-E-1
F Contract Agreements and Biocodes 4-F-1
G Biotechnology Classification System 4-G-1
H Firms' Research Areas by Biocode 4-H-1

Chapter 5 Bioscience Research Programs and Resources at Major Bay Area Universities: A Sample Survey

Introduction 5- 3
Survey Method 5- 3
Summary of Responses to Interview Survey 5- 4
Research Funding 5- 4
Significance of Research 5- 5
Research Facilities 5- 6
Training 5- 7
Prospects for Commercialization 5- 8
Collaborations 5- 9
Technology Transfer 5- 9
Industrial Support 5-10

Chapter 5 Programs and Resources at Major Universities (continued)

Concerns and Constraints 5-11
Recommendations from Researchers 5-14
Conclusion 5-15

Appendices
Persons Interviewed 5-A-1
Research Staff, Funding, and Areas of Interest 5-B-1
Names of University Bioscience Departments and Research Programs 5-C-1
Interview Questions 5-D-1

Chapter 6 Biotechnology Regulations: State and Federal Regulatory Framework and Local Options

Introduction 6- 3
Federal Regulatory Framework 6- 4
State Regulatory Framework 6- 6
Conclusions: Federal, State Regulatory Systems 6- 9
Local Regulatory Framework 6-11
Conclusions: Local Government Involvement 6-14
Local Government Needs 6-15
Strategic Alternatives 6-16

List of Persons Interviewed 6-20
Bibliography 6-21

Chapter 7 Task Force Meeting Agendas and Minutes

Meeting of August 5, 1987
Agenda 7- 2
Minutes 7- 3
Meeting of September 2, 1987
Agenda 7- 6
Minutes 7- 7
Meeting of October 7, 1987
Agenda 7-10
Minutes 7-11

Chapter 7 Task Force Meeting Agendas and Minutes (continued)

Meeting of November 4, 1987
Agenda 7-16
Minutes 7-17
Meeting of January 6, 1988
Agenda 7-24
Minutes 7-25
Meeting of February 3, 1988
Agenda 7-31
Minutes 7-32
Meeting of March 9, 1988
Agenda 7-38
Minutes 7-39
Meeting of June 4, 1988
Agenda 7-44
Minutes 7-45
Meeting of July 6, 1988
Agenda 7-49
Minutes 7-50
Meeting of September 7, 1988
Agenda 7-54
Minutes 7-55

List of Tables

Table 1 4- 6
Table 2 4- 7
Table 3 4- 8
Table 4 4-10
Table 5 4-12
Table 6 4-13
Table 7 4-14
Table 8 4-16
Table 9 4-17
Table 10 4-20
Table 11 4-21

Maps

Locations of Bay Area Biotechnology Firms 4-18

Introduction

The Executive Summary highlights the process the Task Force used as well as its major findings and recommendations.

Chapter 1 describes the formation and history of ABAG's Bioscience Task Force. Included are the goal statement under which the group operated, the tasks incorporated into the work program, and lists of members, meeting dates, and public forums. Chapter 2 summarizes the Task Force's major findings. Recommendations are listed in Chapter 3.

This report also includes three studies conducted by ABAG staff members. An analysis of the economic aspects of the Bay Area's bioscience companies is included in Chapter 4. Chapter 5 presents the results of a survey of bioscience researchers at four Bay Area universities. Chapter 6 is an analysis of the regulatory environment affecting bioscience activities. Chapter 7 incorporates agendas and minutes from each ABAG Bioscience Task Force meeting.

Obviously, the economic research and regulatory environment of the firms and institutions involved in bioscience activity is in constant evolution. Therefore, this report should be viewed as a snapshot rather than a complete, comprehensive guide to bioscience activity.

Executive Summary

In the Summer of 1987, the Executive Board of the Association of Bay Area Governments decided that there was a need to undertake a comprehensive evaluation of Bay Area bioscience activities. This assessment was to be guided by a specially appointed task force. The formal work of the group was completed in September 1988, and included a review of the regulatory structure, the effect on the Bay Area economy, and the scope of university research.

Task Force Purpose

To examine the potential economic effects of expanding bioscience activities in the San Francisco Bay Area. Findings will assist local governments in understanding the prospects and problems associated with sustaining and expanding these industries.

Membership Composition

Task force had 19 members including elected officials, land use law specialists, environmentalists, university officials, and bioscience industry representatives.

Areas of Focus

Specific areas of task force interest included the extent of bioscience activity in the Bay Area, its economic potential, and the framework and effectiveness of existing regulations. In addition, the task force focused on future opportunities and constraints within this region as perceived by industry and university officials.

Methodology and Approach

The task force held a series of public forums on:

1. The role of the state and federal governments in regulation and promotion
2. Private industry and institutional activities, future plans and concerns
3. Environmental issues relating to public health and safety
4. Building code and operational safety requirements
5. Animal testing in bioscience research
6. Research programs and resources at Bay Area universities
7. Existing and potential employment and revenue from bioscience activities

Definition of Bioscience

Bioscience activities include: 1) the research, production or commercialization of biological or chemical processes (known as biotechnology); and 2) the application of physics or development of instruments and software used to support biotechnology (known as biomaterial technology). Together these activities are called the Bay Area's "bioindustry" for purposes of economic analysis.

Highlights of Findings

1. The San Francisco Bay Area is considered the premier center of bioscience and bioindustry due to the number and quality of research professionals, university research facilities, proliferation of high tech companies, and availability of venture capital.

2. Over 100 bioindustry firms in the Bay Area (with 50 or more workers)employ over 19,000 persons. Their 1987 sales exceeded $2 billion. By the year 2000, as many as 60,000 to 120,000 Bay Area residents could be employed in bioindustry. The upper employment estimate of 120,000, should it be reached, equals about half the number of Bay Area residents working in high technology companies in 1980. Therefore, bioindustry could have a significant impact on the Bay Area economy, although not as large as the impact from high technology (electronics, computer, and instrument companies).

3. The existence and growth of Bay Area biotech facilities is related largely to the existence of major university research facilities at UCSF, Stanford, and UC Berkeley.

4. Employment grew 32 percent and revenue grew 51 percent in the Bay Area's bioindustry between 1985 and 1987.

5. Bay Area bioindustry is concentrated within Alameda, San Mateo, and Santa Clara counties.

6. Many university research facilities are in the process of expansion and consolidation. All four leading Bay Area universities are facing opposition from neighborhood groups, animal rights activists, and some environmentalists to construction of new biotech-related research facilities.

7. The future expansion of bioindustry in the Bay Area will be positively influenced by an adequate supply of affordable housing, an effective transportation system, and a responsive and receptive political environment.

Highlights of Recommendations

The Task Force has formulated recommendations on public education and promotion, public concern and regulation, and regional economic impact. Important recommendations are:

1. Establish a regional bioscience center. This center could foster technology transfer and commercialization between university research and private business, facilitate communication on regulatory and economic issues, and promote the region throughout the world as a leader in biosciences.

2. Hold workshops for local officials on the importance of bioscience to Bay Area residents and our economy, the structure of state and federal regulatory systems, and the opportunities and constraints of local regulation.

3. Collaborate with state and federal regulators before adopting unique local restrictions on bioscience activities. The present framework of regulations relies heavily on state and federal agencies. To strengthen and maintain effective public policy, these agencies need to consider and respond to local concerns.

Chapter 1

Formation and History:

ABAG's Bioscience Task Force

History

The San Francisco Bay Area has benefited tremendously from being the home of the high tech revolution. Not only has that industry provided jobs for many Bay Area residents, but also the region has experienced a significant gain in total personal income.

Regional planners for the Association of Bay Area Governments, as well as others believe that the emerging bioscience industry -- also centered in the Bay Area -- could offer continued economic prosperity for area residents. However, with increased public awareness of the risks, or perceived risks, of bioscience, public and private leaders decided to convene a forum to study the implications of increased bioscience activity for the Bay Area. Silicon Valley had occurred spontaneously, without government intervention, but a similar phenomenon for biosciences seemed doubtful. In fact, local leaders realized that the Bay Area's leadership in bioscience research would probably need a public-private relationship which would establish a balance between important environmental and economic concerns.

Formation

During the first half of 1987, ABAG staff in cooperation with Richard Morten of the San Francisco Chamber of Commerce and Edward Blakely of the University of California, Berkeley, started discussing the formation of a committee to examine:

- Potential economic and social effects of expanding bioscience activities in the Bay Area, and
- Problems and prospects of sustaining this type of industry.

ABAG's Executive Board decided to appoint a task force to examine the economic effect of an expanding bioscience industry on the Bay Area and to formulate recommendations for universities and industry as well as for local, regional, state, and federal governments.

Membership

Care was taken in choosing members to balance industry representatives with environmentalists and other community spokespersons. Consideration was also given to having representatives from various parts of the region.

The nineteen people appointed to ABAG's Bioscience Task Force included:

- local elected officials;
- land-use law specialists;
- environmentalists;
- university officials; and
- bioscience industry representatives.

Meetings

Over a one-year period starting in August 1987, the Task Force held nine meetings. By September 1988, the group had heard testimony from numerous sources and had finalized recommendations for local governments, state and federal agencies and legislators, and bioindustry. The well-attended meetings were open to the public and received media coverage.

Work Program

The ABAG Bioscience Task Force was established to confer for a limited number of meetings and report its findings and recommendations to ABAG's Executive Committee. Based on comments from members and other interested parties the ABAG Task Force defined its mission:

The goal of this Task Force is to encourage the evolution of bioscience activities in the Bay Area consistent with the protection of public health, safety, and the environment. The charge of the Task Force is to better understand the broad spectrum of activities, industries, firms, and institutions that are covered under the aegis of bioscience in the Bay Area; its competitive position, the constraints to its development, and the associated

public concerns, costs, and benefits. The Task Force will make recommendations to the ABAG Executive Board on a broad spectrum of issues. These may include, but not be limited to, educating both the public and elected officials on the potential of this broad activity and making policy recommendations with respect to consistent land use and health and safety controls so as to strengthen the region's economic competitiveness and its institutions for bioscience.

A work program was adopted with these specific objectives:

- identify and record the extent and potential of bioscience activity in the Bay Area;
- understand how university bioscience research is dynamically linked to industry growth;
- document the regulatory framework which is applied to bioscience activities;
- consider how public concern about bioscience can be incorporated into the decision process; and
- develop recommendations.

These objectives were developed into specific tasks:

Task 1

Identify and record the extent of bioscience activity in the Bay Area, in terms of the number and geographic distribution of firms and research institutions, and the substantive areas in which Bay Area firms operate. Describe the programs and resources that exist in the major universities and extend beyond bioscience research into public education and awareness.

Task 2

Identify the economic potential of bioscience activities and compare this potential to that of high tech industry. Will bioscience help maintain or encourage diversity within the Bay Area's economy? Assess the employment and overall growth potential of specific types of firms and institutions using national, state, and regional data.

Task 3

Identify the extent to which local biotech activity provides additional purchases, employment, tax revenue, and other public and private benefits within the Bay Area. Identify the extent to which emerging biotech research interacts with existing Bay Area businesses and educational institutions.

Task 4

Identify existing federal, state, and local regulations that affect bioscience activities. Postulate how interaction should occur at the local level.

Task 5

Identify public concerns relating to bioscience activities. Focus on environmental safety and health issues. Attempt to identify potential risks as well as possible public fears and how local officials might respond.

Task 6

Identify the concerns of bioindustries about local land use and other regulations. Identify public constraints to the growth of bioscience activities.

Task 7

Identify a path of action for the public sector, namely, what actions local governments should take to promote and sustain bioscience activities in the Bay Area while also protecting public health, safety, and environmental factors.

Public Forums

Public forums were held on these topics:

- Role of state and federal governments in regulation and promotion
- Private industry and institutional activities, future plans, and concerns
- Environmental issues relating to public health and safety
- Building code and operational safety requirements
- Animal testing in bioscience research
- Research programs and resources at Bay Area universities
- Existing and potential employment and revenue from bioscience activities

Chapter 7 includes agendas and minutes of each meeting or public forum. The names of those presenting information or speaking at each meeting are incorporated into the minutes.

Chapter 2

Task Force Findings

The findings of the Task Force were derived from research by ABAG staff members, testimony presented to the Task Force, and opinions presented by Task Force members. Some of these ideas were clearly evident from the beginning; others were recognized gradually as a result of public hearings and discussions.

The major conclusions of the findings are stated below, with a fuller discussion of each in the following pages.

- The Bay Area leads in bioscience and bioindustry.
- Bioindustry contributes to an expanding area economy.
- Continued bioindustry growth depends on synergy between bioindustry and university bioscience research.
- Bioscience regulation necessary for public acceptance.
- A skilled bioscience work force needs access to training.
- Few are well-informed about bioscience technical issues.
- Maintaining the Bay Area as a bioscience center will be important to our economy.

The Bay Area Leads in Bioscience and Bioindustry

- *The Bay Area is the World's Premier Bioscience Center*

The Bay Area has achieved its prominent position in bioscience because it is the home of: 1) world class universities and laboratories doing advanced biological and genetic research; 2) leading high tech and bioscience research and development firms; and 3) important venture capital companies.

Bioindustry Contributes to An Expanding Area Economy

- *Employment Increased 32 Percent from 1985 to 1987*

The San Francisco Bay Area economy has benefited from being the home of the bioscience revolution. As industrial spinoffs have occurred, jobs were created and total personal income rose. More than 100 bioindustry firms with over 50 employees located in the region employ 19,000 persons and sell over $2 billion per year. The industry experienced a 32 percent growth in employment and a 51 percent increase in revenue between 1985 and 1987. Biomaterials firms that produce instruments are forecast to grow faster than biotechnology businesses.

- *Bioindustry Expansion Helps City Redevelopment*

Bioindustry clearly offers redevelopment potential to those parts of the Bay Area with a declining industrial base and opportunities for growth. To date, bioindustry firms are concentrating in the older industrial areas of Alameda and San Mateo counties and in Santa Clara County.

- *Area Business Benefits From Bioindustry Expansion*

Existing Bay Area service and industrial businesses are being positively affected by bioindustry's growth because, as suppliers and sellers for the industry, their business has expanded.

- *Royalties from Bioscience Patents Help Universities*

All major Bay Area universities hold bioscience patents. In 1987, 50 percent of Stanford's patent income was derived from royalties on bioscience research.

Continued Bioindustry Growth Depends on Synergy between Bioindustry and University Bioscience Research

- *Biotechnology Relies on University Research*

Significant bioscience research exists at the University of California's San Francisco, Berkeley, and Davis campuses as well as Stanford University. University research tends to focus on basic scientific research; private businesses extend that research to specific commercial applications. Because only a few companies can afford to conduct university-type research, most bioindustry firms continue to look to universities for innovation, discovery, and application of biological products.

- *University Research Facilities must be Upgraded*

Many of the university researchers ABAG interviewed stated that, if their research facilities are not upgraded periodically, they cannot continue to attract top students, perform state-of-the-art research, or convert that research to public benefit.

- *Opposition has Delayed New Research Facilities*

All four universities surveyed are experiencing delays in new bioscience research laboratory construction due to opposition from certain segments of the public: neighborhood groups, animal rights activists, and some environmental groups. Although the nature of each dispute is unique, the underlying reasons for the opposition, according to academic researchers interviewed, are 1) misunderstanding or fear of the science itself; 2) fear and suspicion of the institution where the program is proposed; 3) fear of change and technological accidents; and 4) conflicting political interests among the opponents.

Bioscience Regulation Necessary for Public Acceptance

- *Bioscience Researchers Initiated Self-Regulation*

Public concern seems to be directly related to adequacy of regulations guarding public safety. Both university and corporate researchers recognized early in the development of the discipline that careful consideration of the consequences of their work would be mandatory. For that reason, the industry has supported the creation of what it considers to be reasonable, well-defined, and consistent regulations.

- *Significant Government Controls Created Prior to Any Major Research or Industrial Accident*

Bioscience is one of the few industries which has been subjected to significant health and safety controls before any hazard has been proved or any accident has occurred. This is particularly unusual given the type and quantity of regulations which have been proposed.

- *University Safety Procedures Often are More Stringent Than Required by Law*

University researchers and officials claim that campus environmental safety systems, procedures, and facilities are designed to respond to any potential hazard to humans or animals from biological, chemical, or radioactive materials. Most new researchers state they are required to pass safety, training and certification tests, which are more stringent than those required by law.

- *Existing Laws May Adequately Cover Bioproducts*

Both the federal Biotechnology Science Coordinating Committee and the State's Interagency Task Force on Biotechnology have concluded that existing laws and regulatory authority now cover the wide range of biotechnology products and processes. Any new bioengineered materials not already regulated by another agency will be handled under EPA's Toxic Substances Control Act (TOSCA) as a "new chemical."

- *Jurisdictional Overlap Provides Additional Safeguards*

Some definitional discrepancies and areas of ambiguity remain. All state and federal agencies are conducting reviews on a case-by-case basis. The existence of overlapping agency jurisdictions seems to provide necessary assurance that all activities are covered.

- *Guidelines, Permitting Procedures Need to be Finalized*

While most parties -- government, industry, university researchers, and the public -- agree about the need for regulations, the development of certain recommendations has lagged. For example, implementing regulations for the 1985 amendments to the Animal Welfare Act have not yet been finalized. The State's work to clarify how agencies' procedures should incorporate environmental clearance also needs to be completed.

- *Public Looks to Local Government for Protection on Biotechnology Issues*

Local governments have been responsive to public concerns about biotechnology. This is because, although biotechnology activities will benefit the region, the state and the nation, as well as the immediate locality, the risk, should an accident occur, will be borne mostly by nearby residents.

- *More Communication Needed between Federal, State and Local Officials*

The network of federal and state regulatory agencies is often confusing and unpredictable to local government officials and to the public. Conversely, state and federal staff have not worked as closely as they might have with local government.

- *Both Bioindustry and the Public are Affected by Weak Inter-Governmental Cooperation and Communication*

Although bioindustry and university researchers have tried to comply with government regulations, considerable delays have occurred because members of the public are not knowledgeable about existing safeguards and thus are concerned about whether they are being sufficiently protected.

- *Local Governments Need Some Bioscience Knowledge*

Applications for new research laboratories and industrial facilities can be expected to increase. Although most local governments will defer technical regulation to federal and state agencies, they will still be responsible for reviewing development plans, use permits, and plans for materials storage and handling. Staff members reviewing these applications will need to understand economic, safety, and environmental risk factors. Few communities have staff with sufficient expertise to understand technical bioscience issues.

- *Most Local Governments are Unprepared to Process Permits Involving Biotechnology*

Given time limits prescribed by state law for processing development permits, local governments that wait until they receive an application may not have time to identify and investigate appropriate approval provisions. Before issues arise, it is important for local governments to become familiar with the regulations and formulate a course of action appropriate for their community.

Skilled Bioscience Work Force Needs Access to Training

- *A Labor Force Trained for Bioscience Work is Crucial to Continued Bay Area Bioindustry Development*

Well-tailored and broad-based bioscience training and educational programs will be crucial to continuing bioscience industrial development. When the industry becomes more capital intensive, a skilled labor pool will be of greater importance to sustained growth.

- *Special Training will be Required Even for Service Workers Employed in Bioindustry Jobs*

Public and employee safety will involve advanced training for all levels of bioscience workers, including, for example, janitorial workers. These people will be working with sophisticated, expensive, and possibly hazardous materials and equipment.

- *Area Colleges will Need to Develop Training Programs*

According to university researchers, the types of institutions most suitable for the training of supportive researchers and technical service personnel are state universities, community colleges, or extension services.

Few are Well-Informed About Bioscience Technical Issues

- *Public Will Need More Information About Bioscience to Feel Reassured*

Researchers and university officers believe that the public would be less fearful of bioscience projects if it knew more about the operating methods which have been established to avoid accidents inside and outside the laboratory. The bioscience community itself admits that more should have been done earlier to communicate with community groups. Every researcher interviewed wants to participate in public education. and wants avenues to communicate with neighbors before issues reach a crisis.

- *Information Needed on Several Levels*

First, people will need information in order to understand more clearly what bioscience is and what its potential benefits and risks are. Second, knowledge of the federal and state regulatory process for bioscience is necessary in order to know how well the public is protected. Third, using less technical language when publicizing bioscience proposals could help public understanding and acceptance.

Maintaining the Bay Area as A Bioscience Center will be Important to Our Economy

- *Decision-makers and the Media Need to Become More Knowledgable about Bioscience*

Elected officials and their staffs, as well as the media, will play an important role in determining whether the Bay Area will continue to be the world's leading bioscience center. These parties need to balance safety concerns with potential economic benefits in order to formulate laws and implement regulations. This will require some understanding of a myriad of technical bioscience issues.

- *Securing Capital for Bioscience Projects in the Bay Area Depends on Public Acceptance*

Researchers report that bioindustry needs realistic, long-term support from local governments in order to attract domestic and foreign investments. A positive public image is becoming more important to obtaining capital and securing corporate approval for expansion within the Bay Area. If Bay Area residents and decision-makers fail to support such growth, the industry will probably develop where conditions are more hospitable.

- *Early Designation of Locations Suitable to Bioindustry*

Instead of waiting to receive applications, communities interested in attracting or holding onto bioindustry should consider designating permissible locations for such facilities as well as procedures for special materials storage and placement. Bioindustry could better respond to a community's desires if some forethought were given to these issues.

- *Provide for Future Labor Supply*

Adequate housing in proximity to existing and future employment centers as well as an effective transportation system are important to the continued vitality of Bay Area bioindustry.

- *As Biotechnology Firms Mature, They Could Expand Elsewhere*

Firms using biotechnology in their production process have substantial barriers to entering the market. The industry has been adjusting to these constraints by creating agreements, partnerships, and joint ventures with other firms, particularly multi-national companies.

Of the Bay Area biotechnology firms with fifty or more employees, 41 percent are owned by multi-national companies. Another 14 percent have agreements with such firms. This ownership structure may hinder the long-term growth of this industry in the Bay Area because as the industry matures, and companies start developing more administrative, marketing, and production facilities, their non-Bay Area partner may urge consideration of other, more cost-effective areas. These pressures to locate outside the Bay Area are similar to those encountered by other businesses.

Chapter 3

Task Force Recommendations

The Task Force considered and adopted recommendations on public education, promotion, and regulatory issues including animal welfare. Most of the recommendations were considered first by one of two small working groups of Task Force members and then forwarded to the entire Task Force for approval.

Recommendations on Public Education and Promotion

The Task Force agreed that information is needed on several levels. First, people need to understand what bioscience is as well as its potential outcomes. Second, people need to understand how federal and state regulations are promulgated and enforced in order to evaluate how well the public is being protected. Third, people need to be aware of their options relating to specialized regulations and promotional efforts.

The following program is designed to help elected officials and their staffs understand the implications of bioscience for this region, its cities, and counties.

Regional or Subregional Workshops

Hold periodic sessions, directed toward elected officials and their staffs, which would concentrate on:

- the structure of the state and federal regulatory system;
- how local regulation has been approached and whether it is necessary; and
- the economic and social importance of bioscience to the Bay Area economy.

Such workshops should be free or cost only a minimal amount to encourage participation. Speakers could include Task Force members, experts, and special interest groups. ABAG would cooperate with other organizations in sponsoring such events.

Center for Biosciences

Create a center for biosciences which would serve Bay Area university researchers, industry, local government, and the public, and also serve as the core of a strategy for continued Bay Area leadership in bioscience. The center would seek to:

- enhance excellence in basic and applied research;
- foster technology and communication between university research and private business;
- increase public awareness in support of bioscience research and applications; and
- promote the region throughout the world as a leader in biosciences.

Finally, the center could serve to maximize public awareness about the field of bioscience and could function as a communications center on social and economic issues.

Bioscience Resource Clearinghouse

Establish a library of information relating to public policy issues and regulations associated with bioscience activities. Such a clearinghouse could serve as a repository for the diverse and growing amount of material being issued on bioscience. This information would be available to both the public and business and could possibly be part of the Center for Biosciences.

Recommendations on Regulatory Issues

The Task Force believes that it is necessary for all parties associated with bioscience activity, whether from the public or private sector, to aggressively address public concerns. The nature of bioscience activity can lead to public insecurity, misunderstanding, and overreaction. One way to minimize this is to fully accommodate public questions and concerns within the existing regulatory framework and to adopt or modify local regulations only when absolutely necessary.

Separate recommendations were adopted for 1) research Institutions and bioscience companies, 2) local governments, 3) regional agencies, and 4) the federal and state governments.

Recommendations to Research Institutions and Bioscience Companies

The following recommendations are intended to be used as guidelines by firms and institutions in their future operations.

Bioscience companies and research institutions need to:

1. Consider adhering to the National Institutes of Health (NIH) Guidelines.

2. Support and implement reasonable state and federal regulations governing research, development, manufacturing, distribution, and disposal of bioscience materials and products.

3. Accept the need for full disclosure of information related to public health, safety, and welfare effects under the California Environmental Quality Act (CEQA) and other laws. In preparation for deliberate release testing or production, companies should allow sufficient time for public review and comment, and should include communication with the local community.

4. Actively support efforts to improve public awareness and acceptability of this technology. This might include participating in meetings of local homeowners, industry associations, PTA's, service clubs, the League of Women Voters, etc.; and inviting and encouraging public officials (City Council, Planning Commission, staff) to visit and be informed about this technology and its applications.

Recommendations to Local Governments

Before deciding to adopt their own specific bioscience regulations, local governments need to determine the extent of the authority and control already available to cities, counties, and special districts under existing permitting procedures; and the opportunities for local participation in existing state and federal bioscience permitting and enforcement activities.

Local governments also need to:

1. Become more well-informed about bioscience industries, institutions, and their regulatory framework. Public officials responsible for decision-making on bioscience activities can anticipate and prepare by acquainting themselves with the issues, and actively promoting citizen awareness.

2. Recognize that the adoption of special local regulations applicable to bioscience activities could affect the retention and attraction of such business and institutional activities. Information required as part of any local permitting procedure may need to be considered proprietary and therefore protected.

3. Be aware that development of a local regulatory program specifically for bioscience activities will require additional funding and could be cumbersome. Local governments may want to consider how their more active participation in state and federal enforcement and permitting activities could satisfactorily substitute for locally mandated enforcement provisions.

4. Consider remedying any deficiencies in the regulatory framework by collaborating with federal and state regulators before adopting unique local regulations. ABAG will assist its member cities and counties in recommending changes to state and federal laws and procedures.

5. Consider their potential liability, should they choose to regulate bioscience activity locally. For example, were a local government to adopt its own inspection program, what liability could be incurred, should a serious accident occur?

6. Amend local zoning ordinances to specify in which districts bioscience activities will be allowed and whether use permits will be required for such activities. Ordinances should address the possibility of both office and laboratory activities.

7. Adopt amendments to the Uniform Building Code, as they are issued, which relate to high technology and bioscience.

8. Invite state and federal regulatory officials to conduct local public meetings prior to deliberate-release field tests, laboratory certifications, or other major permitting procedures.

9. Advise agriculture commissioners and health officers, who receive the official state notification of applications for deliberate-release testing, that they should inform a broader range of public officials, citizen groups, and the media. When notifying these parties, non-technical language should be used as much as possible.

Recommendations to Regional Agencies

The Association of Bay Area Governments needs to serve as a regulatory communication, information, and resource agency for local government, including the facilitation of workshops, seminars, and information exchanges between local and state governments.

The Association of Bay Area Governments and those agencies responsible for regional air and water quality need to:

1. Periodically review the need for supplemental bioscience regulation and, whenever necessary, strongly encourage state or federal measures to address local concerns. ABAG should coordinate local government recommendations on modifications in state and federal regulations.

2. Advise local agencies of the existing regulatory system and persons who can be contacted for further information.

3. Advise local agencies of pending or proposed changes to regulatory system so that they can make early comment.

Recommendations to State and Federal Agencies

The framework of regulations affecting bioscience activity currently relies heavily on state and federal agencies. Although this structure exists, it places pressure on these levels of government to address local concerns. Public perception that state and federal agencies have failed to adequately address local concerns is causing city and county governments to consider adopting their own regulations.

State and Federal agencies need to:

1. Encourage all businesses and laboratories involved in bioscience to adhere to the NIH guidelines. Such an action would be intended to head off the need for mandatory conformance and inspection requirements.

2. Make information widely accessible at the local level when a decision is being considered. For example, notifying county health officers and agricultural commissioners about intended deliberate-release programs does not always provide elected officials or the public with adequate information about bioscience activity. To address this concern the state should, as a matter of course, also notify the local jurisdiction's chief executive officer.

3. Continue the recent decision to incorporate site visits in the review of applications for environmental release of new biotech products.

4. Appoint local public members as well as technical and business representatives to new bioscience advisory boards.

5. Clarify the relationship between state bioscience regulatory activities and the California Environmental Quality Act.

6. Conduct regular, periodic workshops or seminars on regulatory and scientific issues relating to bioscience activity with local and regional agencies.

7. Strive to make any information released to the public or local officials as clear and non-technical as possible.

Recommendations on Animal Use in Research

The Task Force received public testimony about the use of animals in bioscience research. This was followed with a request to over 50 individuals and groups for specific information about how animals are being used in the Bay Area for such research. These individuals and groups were also asked to submit ideas for related recommendations that the Task Force

could consider and possibly adopt. The Task Force members subsequently received more testimony on the animal welfare issue as it pertains to bioscience research and deferred the issue to staff for a recommendation.

Recognizing that animals are used for research in Bay Area companies and educational institutions, and that considerable publicity and concern have surrounded the question of whether those animals are being treated humanely, the Task Force concluded it needed to adopt pertinent recommendations which accommodate 1) the public concerns such as humane animal treatment during research, and 2) the requirements of an emerging industry which could contribute to the continued economic prosperity of Bay Area residents.

Recommendations To Bioscience Companies and University Researchers

1. Recognize that the humane treatment of animals is an issue which is important to a significant portion of the nation's population, and particularly Bay Area residents. Therefore, the establishment of and adherence to standards of humane animal treatment need to be an integral part of a company's successful business strategy and an educational institution's public service mission.

2. Appoint independent representatives to animal care committees who reflect concerns about the humane use of animals in research.

3. Help minimize community concerns by voluntarily adhering to the standards on use of animals in research which have been developed by the National Academy of Sciences for the National Institutes of Health and which are used by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

4. Consider alternatives to research on animals whenever feasible.

5. Consider the unique characteristics of the species which will be housed, when building or renovating animal facilities.

Recommendations To Local Governments

1. Before adopting unique local regulations, local governments should consider the existing federal and state regulations governing the humane care and use of laboratory animals, determine whether or not the existing regulatory framework is deficient in meeting local needs, and communicate their concerns to the appropriate regulatory body. Local governments sharing similar concerns are encouraged to forward their communications through an organization such as ABAG.

2. Urge bioscience companies not already required under federal or state regulations to establish animal care committees which include independent community representatives. Such representation should reflect the community's concerns about use of animals in research.

3. When animals are to be used for research, adherence to standards developed by the National Academy of Sciences for the National Institutes of Health and which are used by the American Association for Accreditation of Laboratory Animal Care (AAALAC) is preferred, particularly for large companies and educational institutions.

4. Indicate to bioscience companies desiring to locate within the community that, whenever feasible, they should consider alternatives to research on animals.

5. Be aware that, in addition to the issue of the humane treatment of animals, animal rights advocates have significant concerns regarding the legal and ethical implications of patenting or other uses of life forms that may be the result of such research.

Recommendations To State and Federal Officials

1. Review and update pertinent laws and regulations regularly. Local officials need to rely on the laws and regulations of those higher governmental units which already monitor animal use in research. Not keeping regulations responsive to public concerns may encourage more local regulatory actions.

2. Finalize proposed regulations within a reasonable time after laws are changed. Implementing regulations for the 1985 amendments to the Animal Welfare Act, the first draft of which was issued in March 1987, should be finalized as soon as possible.

Chapter 4

Bay Area Bioindustry: Structure, Constraints, and Potential

Chapter 4

Contents

Summary Page 4- 3

Introduction Page 4- 4

Overview: Bay Area Bioindustry Page 4- 5

Industry Classification Page 4- 7

Changing Organizational Base Page 4- 9

Research Concentration of Biotechnology Firms Page 4-12

Product Development Links to Multi-National Firms 4-15

Location within the Bay Area Page 4-17

Local Economic Impacts Page 4-19

Public Policy Implications and Growth Potential Page 4-22

Recommendations Page 4-24

Conclusions Page 4-25

Afterword Page 4-25

Footnotes Page 4-26

References Page 4-27

Appendices - Bay Area Bioindustry Firms

A	Names and Locations	Page 4-A-1
B	Description and Year Founded	Page 4-B-1
C	History and Financial Status	Page 4-C-1
D	Employment and Operating Statistics	Page 4-D-1
E	Links to Multi-National Firms	Page 4-E-1
F	Agreements and Biocodes	Page 4-F-1
G	Biotechnology Classification System	Page 4-G-1
H	Firms' Research Areas by Biocode	Page 4-H-1

Summary

This chapter focuses upon San Francisco Bay Area bioindustry. The word bioindustry is used to define two primary forms of economic activity. 1) firms using biotechnology as a process to produce biologicals and chemicals, and 2) those firms using engineering, physics, and materials technology to produce instruments and software to support world-wide markets of industries using biotechnology.

The industry remains relatively small in comparison to the semiconductor and computer industry in the Bay Area, but its growth rate has been substantial in recent history. Between 1985 and 1987, employment in the Bay Area bioindustry grew by 32 percent. Revenues over this same period increased by 51 percent in inflation-adjusted dollars. Materials technology firms are the fastest growing in terms of employment: by the year 2000, the industry may have as many as 122,000 jobs. The growth rate, however, is highly uncertain.

Firms using biotechnology in their production process encounter substantial barriers to entering the market, such as lead time in product development, research requirements, intense competition, and government regulations. The industry has been adjusting to these constraints by agreements, partnerships and joint ventures.

In 1987, nearly 41 percent of the firms in the Bay Area engaged in using biotechnology were owned by multi-national corporations. This ownership structure may help in the initial stages of firm development but may hinder long-term growth in the Bay Area. Other Bay Area industries that are affected by growth of the bioindustry are identified. Finally, recommendations are also presented for improving the economic environment of this industry.

Introduction

Bioindustry includes two activities:

1) Firms using biological or chemical processes; and
2) Firms using materials technology.

This report focuses on the bioindustry in the Bay Area and is limited to looking at the private sector of bioscience research, development, and manufacturing. Bay Area bioindustry is classified into two component parts: the research, production or commercialization of biological or chemical processes, and the physics and materials technology used to support biotechnology. Andrew J. Hacking in his book, "Economic Aspects of Biotechnology" (1986), states that "Biotechnology is not an industry defined by products or services... It refers to the use of microbial, animal or plant cells and enzymes to synthesize, break down or transform materials. It is a means of production."

Reference in this report to biotechnology specifically is associated with biological or chemical processes used as a means of production. Genetic engineering is the key research tool that facilitates these biological or chemical processes. Companies using biotechnology supply products and services which span a range of applications from food to fuel, from waste disposal to pharmaceuticals. For the purpose of this study, these firms are called cellular and molecular engineering firms.

Correspondingly, biomaterials technology refers to instruments, software, or the application of physics to facilitate biotechnology research and development. Therefore, companies engaged in this type of production focus a major portion of their activity on servicing the needs of industries using biotechnology to produce products or services. These businesses are classified as biomaterials firms.

The bioindustry in the Bay Area is rapidly growing. The data analyzed, while still limited, show the extent of this economic activity in the Bay Area. Although the industry is often characterized as an "emerging industry," the facts show that the industry is well established in the Bay Area and that it continues to expand in importance as a source of employment, wealth creation, and knowledge production. Overall industry employment and revenue estimates are greater than reported in this study because of the limited data sources and because many private companies consider such information as confidential. It

is clear that several biotechnology firms in the Bay Area are moving toward becoming major pharmaceutical firms in the international marketplace.

The large number of firms involved in biotechnology and material technology will likely lead to a market adjustment. A market adjustment occurs when the number of firms exceeds the ability of the market to absorb their products. This adjustment will either drive a substantial number of firms out of the market or result in the consolidation of others into larger firms. Biotechnology is today a technology in search of applications. It requires a high degree of innovation and is subject to the frailties of financial market fluctuations (e.g., decline or lack of growth in stock prices for public companies for reasons independent of the firm). Given this instability of the market and research environment, it is essential that public policy provide consistent and well defined rules and regulations.

Overview: Bay Area Bioindustry

The dynamics of a healthy economy require continuous evolution of its industries. In the Bay Area, the semiconductor and computer industries are major contributors to the success of this region's economy. Attention is now being drawn to an emerging industry -- the bioindustry -- as a potential new industry in the evolution of the Bay Area economy. The bioindustry firms focusing on using biotechnology as a means of production, and those firms using materials technology to support and promote production using biotechnology, have been in the Bay Area for a long time. In 1987, there were an estimated 112 bioindustry firms in the Bay Area. Appendix A identifies these firms. Of this total, 46 had more than fifty employees. **This report limits its scope to the larger sized firms primarily because these are the firms for which data are available.**

46 of the 112 Bay Area bioindustry firms had 50 employees or more in 1987.

In 1987, there were an estimated 19,400 jobs in Bay Area bioindustry firms employing fifty or more individuals. These firms had total sales estimated at more than $2 billion in inflation-adjusted 1985 dollars.

Bioindustry employment increased to 19,400, or 32 percent between 1985 and 1987.

Between 1985 and 1987, the Bay Area bioindustry firms identified in Table 1 had a 51 percent increase in inflation-adjusted sales and a 51 percent increase in employment. Overall employment increased by only 3.1 percent in the Bay Area during the same period.

Table 1 identifies historical and estimated 1988 employment and total sales for Bay Area bioindustry firms. Note that the data shown below reflect historical and projected employment and revenue data only for firms with 50 or more employees. Therefore, these estimates should be considered conservative by at least ten to fifteen percent.

Table 1

Bioindustry Employment and Revenues: San Francisco Bay Area

Employment	Revenues	Constant 1985 $ (in billions)
1985	14,650	$1.352
1986	16,540	$1.610
1987	19,400	$2.047
Growth 1985-87	32%	51 %
1988 Forecast	$21,900 - 22,700	$2.40 - 3.70

Sources: ABAG; Annual Reports of bioindustry firms.

Industry Classification

The bioindustry is a difficult industry to classify because of the nature of production activity. This is particularly true of firms using biotechnology. Considerable effort went into defining the Standard Industrial Classification of these firms using the **1987 Standard Industrial Classification Manual** published by the Executive Office of the President, Office of Management and Budget, Washington, D.C. This latest classification system attempts to better identify the technology changes that have occurred in industry since the previous SIC Manual. Using the 1987 manual, the Bay Area bioindustry was divided into two component parts. Table 2 identifies the standard industrial classifications for each.

Table 2

Standard Industrial Classification of Bay Area Bioindustry

	Biotechnology Activity	Materials Technology
SIC	2833, 2834, 2835 2836, 2879, 8731, 8733	3826, 3829, 3841, 7372

Sources: ABAG; 1987 Standard Industrial Classification Manual, Executive Office of the President, Office of Management and Budget.

Using the above classification system, employment estimates and forecasts for the bioindustry were divided into two groups as identified in Table 2. This division provides a clearer understanding of the distribution of jobs, because of how jobs are classified, and permits a more detailed analysis of the type of production service performed by each firm. Table 3 summarizes these data.

Table 3

Estimated Number of Persons Working For San Francisco Bay Area Bioindustry Firms With 50 Or More Employees[1]

	Total	Biotechnology Activity	Materials Technology
1985	14,650	8,813	5,837
1986	17,540	9,622	7,918
1987	19,400	10,874	8,526
1988	21,900 - 22,700	11,800 - 12,000	10,100 - 10,700
1990	26,700 - 30,500	13,900 - 14,900	12,800 - 15,600
2000	60,600 - 122,800	26,800 - 42,800	33,800 - 80,000

Source: ABAG.

Materials technology firms will grow faster than other bioindustry companies.

A range forecast is presented to show uncertainty and to assess the maximum potential of the bioindustry, based on a given time frame and on limited information on the technology base.

There are some discernible trends that can be identified that will help in understanding the overall growth potential of this industry. Historical data from 1985 to 1987 show a shifting trend toward faster growth in the materials technology component of the bioindustry than the biotechnology component. In 1985, 60 percent of the employment in bioindustry was in the biotechnology sector. By 1987, that fraction had declined to 56 percent. This shows the growing importance of the materials technology sector in the bioindustry.

It should be expected that the materials technology sector would grow at a faster rate than the biotechnology activity sector. Barriers to market entry are fewer; start-up and lead-time costs are less significant, and production can be more varied and demand more diverse. **This does not, however, suggest that the biotechnology activity is any less important. Rather, it is the sector that drives the overall growth in the bioindustry.**

The materials technology sector functions to service the needs of biotechnology research and production. As such, the health of the materials technology industry is directly dependent upon the expanding research and production activity of firms using biotechnology.

In the Bay Area, there is a clear synergy between these two sectors of the bioindustry. Biotechnology research and production in the Bay Area is influenced by the presence of research and educational institutions, and by the presence of the high technology industries which permit closer collaboration between physics and materials engineering with biology and chemistry.

At the same time, the rate of innovation in the materials technology sector of the bioindustry appears to be highly influenced by the rate of innovation in research and production activity in the biotechnology component of the bioindustry.

Changing Organizational Base

Discussion up to this point has focused upon the division of the bioindustry in terms of production and potential employment growth. It is also useful to look at the changing organizational base of biotechnology firms in the Bay Area. **It is emphasized that there is far more need for economic research in this area, and that the conclusions should be viewed as tentative.**

Table 4, presented below, shows some structural information for the biotechnology firms in the Bay Area. Using data gathered from the biotechnology firm Chiron Corporation as a "typical

Manufacturing's share of total employment in biotechnology activity firms increased between 1985 and 1987.

cellular and molecular engineering firm," an estimate was developed of the structural profile and average employment of all firms using biotechnology activity. Average employment was used as a predictor of the fraction and type of activity within each firm.

Table 4

Distribution of Employment Activity In Bay Area Biotechnology Activity Firms

	1985		1987	
	Chiron	Industry	Chiron	Industry
Manufacturing	12 %	21 %	23 %	27 %
Research & Development	77 %	69 %	68 %	64 %
Administration & Marketing	11 %	10 %	9 %	9 %
Average Employment	144	245	263	340

Source: ABAG calculation based upon employment distribution as reported by Chiron Corporation's 1987 Annual Report.

As would be expected, the manufacturing share of total employment is increasing as firm size rises. Between 1985 and 1987, Chiron's employment jumped by 83 percent, whereas average employment per firm for all firms using biotechnology as a production process rose by an estimated 39 percent. In Chiron, manufacturing employment almost doubled; whereas, in the whole industry, it only increased from 21 to 27 percent. As Chiron approaches the size of a 'typical' firm, the change in its employment distribution should reflect the industry average.

Some might be surprised by the initial short-term decline in the percentage of jobs in administration and marketing of all biotechnology jobs. However, this slight decline is probably a natural occurrence and a function of the age of the industry and the stage of development of specific firms. Firms will seek to enter the market as rapidly as possible and the production component of the organizational base would tend to benefit. Research and development's share of total employment should continue to decline. This decline reflects the movement of firms from the developmental stage of growth to the production and competition stage in the cycle of firm development. In the next cycle of development, administration and marketing in biotechnology firms should comprise an increasing percentage of total employment.

Research will remain the largest component of bioindustry employment.

This is the model used in many high tech firms. As firms mature and size increases, marketing and administration become more important for control and management within the firm and for expanding and fragmenting markets to increase sales.

A common misperception of the nature of firms using biotechnology in the production process is that the employment distribution is heavily dominated by employees who have doctorates, and that therefore employment opportunities are limited to only the most educated and specialized. Although it is clear that doctorates are necessary and desirable for many in the research and development divisions. A review of a large sample of firms[2] using biotechnology does not support the assumption of a heavy domination of advanced degrees in overall employment among firms using biotechnology as a production process. Of biotechnology firms with 50 or more employees, about 26 percent of the employees and 32 percent of the firms were included in the sample. Of those, 16 percent of the employees had doctorates and 84 percent did not.

Table 5 shows that even among firm sizes, employees with doctoral degrees, as a percentage of all employees, range from a high of 18 percent to a low of 14 percent. This relationship probably is reflective of all high-tech-oriented industries in the Bay Area. That is, semi-conductor and computer firms rely heavily upon individuals with advanced degrees for new ideas and the generation of new products Industry-wide, the fraction of doctorates to non-doctorates is probably smaller.

Firms using biotechnology in their production process are providing employment opportunities for many of our best educated individuals in biology, chemistry, physics, and biomedical engineering in the Bay Area, opportunities that probably would be substantially limited without the presence of this industry.

Only 16 percent of employees in sample had doctorates.

Table 5

Employee's Educational Attainment At Firms Using Biotechnology And Having 50 Or More Employees

Number of Employees	Doctorate	Non-Doctorate
> 1000	14 %	86 %
500 - 1000	18 %	82 %
100 - 499	17 %	83 %
50 - 99	14 %	86 %
Sample's Distribution	16 %	84 %

Sources: ABAG; Bioscan: The Biotechnology Corporate Directory Service (1987).

Research Concentration of Bay Area Biotechnology Firms

Research is an essential first step in product development. In an industry in which barriers to entry are relatively high, research becomes a major activity of the firms and ultimately leads to a high degree of innovation. As shown in Table 4, as much as two-thirds of the employment in firms using biotechnology is concentrated in research and development. Because of the high cost, it is useful to get a glimpse into the broad types of research underway. This gives clues to product development. Table 6 identifies the concentration of research within firms using biotechnology in the production process and also

Table 6

Types of Biotechnology Industry Research
San Francisco Bay Area: 1987

Concentration		Specialization
Agriculture	12 %	Improved Crops Genetic Engineering Nitrogen-Fixation/ Soil Enrichment/ Inoculants
Biotechnology*	18 %	Instrumentation Industrial Enzymes Reagents/ Research Materials
Food/Brewing Industry	3 %	Food Enzymes
Human Diagnostics	25 %	Immunodiagnostics AIDS Tests Infectious Disease Tests*
Human Therapeutics	34 %	Lymphokines/ Immunomodulators Interferons Drug Delivery/Design/ Formulation Vaccines
Veterinary	8 %	Therapeutics Vaccines Growth Promoters

Sources: ABAG; Bioscan: The Biotechnology Corporate Directory Service (1987).

* (Not Elsewhere Classified)

Research is presently concentrated in human theraputics and diagnostics.

shows that in 1987 most of the research activity of firms using biotechnology was in human diagnostics and therapeutics. Obviously, the market potential of specific drugs for treating AIDs or heart ailments or cancer is quite large.

The down side of such a concentration in economic terms, however, is that **once a drug or product is developed, it generally becomes the property of the firm which produced it, and all other firms (unless the development of the drug or product was a joint venture) exit the race**. This is a major entry barrier to firm using biotechnology as a production tool, as compared with firms using materials technology whose major markets are instrumentation and software use.

Most firms are engaged in multiple areas of research and development, further assuring their ability to capture specific markets. Appendices G and H identify research areas and major firms that are using biotechnology to develop products.

Table 7 identifies specific research areas of major firms using biotechnology or materials technology. This table is limited to areas of research and development concentration in which five or more firms are engaged in the specific research area.

Table 7

Concentration of Research and Development Efforts of Bay Area Firms Using Biotechnology[3]

Improved Crops	Instrumentation
Food Enzymes	AIDS Tests
Immunodiagnostics	Infectious Disease Tests
Anticancers	Vaccines
Drug Delivery/Design/Formulation	Hormones (Except Growth)
Interferons	Lymphokines
Veterinary Theraputics	Veterinary Vaccines
Immunomodulators (Except Interferons)	

Source: Bioscan: The Biotechnology Corporate Directory Service (1987).

Product Development Links to Multi-National Firms

Because of the cost of research and development efforts to produce products using biotechnology, many firms form agreements or joint ventures with other Bay Area firms or multinational corporations. Such links share costs and broaden the knowledge base of each firm's researchers who are working on similar problems or who can provide complementary information.

Joint ventures & agreements strengthen the region's bioindustry.

Table 8 which follows identifies local links between Bay Area firms in 1987. From an economic perspective, joint ventures and agreements are positive because they ultimately strengthen the base of the existing industry in the region in competition with firms in other parts of the world. They are designed to maximize the research and development strength of each company in the race to generate new products for the market.

Examining local links to various multi-national corporations(see Appendix E) is more revealing than examining links between Bay Area bioindustry firms. This information is critical from an economic development perspective because the parent organization can substantially affect the development potential of the local firm; regardless of the organizational independence of the local firm, ultimate management control is vested elsewhere. This, in itself, is not significant from an economic development perspective, but it **can** effect expansion and local growth.

The great debate in the last several years over consolidation and buy-outs of Bay Area firms fundamentally rested on loss of local control of the decision process. A company whose corporate decision-making is located elsewhere may decide that a manufacturing facility or a new laboratory might be more efficiently located elsewhere. Decision-making is complicated by a number of factors, including loyalty to a specific location. Of the firms with 50 or more employees in the Bay Area which use biotechnology in the production process, **41 percent are subsidiaries of multi-national corporations and 55 percent have marketing, licensing, joint venture, royalty, and rights agreements with these corporations**.

Table 8

Contractual Agreements, Joint Ventures Among Bay Area Bioindustry Firms 1987

Company	Association	Company
Alza	Agreement	Smithkline
Becton Dickinson Monoclonal	Agreement	Applied Immune Systems
Biosearch	Joint Venture	Hp-Genenchem
Biosearch	Agreement	Applied Biosystems
Cetus	Joint Venture	Triton Bioscience
Chiron	Joint Venture	Barnes-Hinde
Chiron	Agreement	Lucky Ltd.
Cooper Development	Agreement	Chiron Corp.
Cooper Development	Agreement	Bio-Response
Cooper Development	Agreement	Liposome Technology
Genentech	Joint Venture	New Brunswick (Biosearch)
Genentech	Agreement	Cutter Laboratories
Genentech	Joint Venture	Hewlett-Packard
Liposome Technology	Agreement	3-M Diagnostics
Liposome Technology	Agreement	Alza Corp.
Syntex	Agreement	Advanced Polymer Systems
Syntex	Agreement	Genelabs
Syntex	Agreement	American Bionetics
Syva	Agreement	Hana Biologics
Zoecon	Agreement	Sandoz

Sources: ABAG; Bioscan: The Biotechnology Corporate Directory Service, The Oryx Press, Phoenix, 1987

There is no value judgment placed upon whether ownership by multi-national corporations will retard long-term **potential** growth of bioindustry firms in the Bay Area. It is, however, a piece of information needed to properly assess the economic potential of locating and maintaining research and development facilities, and also administrative, marketing and manufacturing activities in the Bay Area.

41 percent of Bay Area bioindustry firms are subsidiaries of multi-national corporations.

Location within the Bay Area

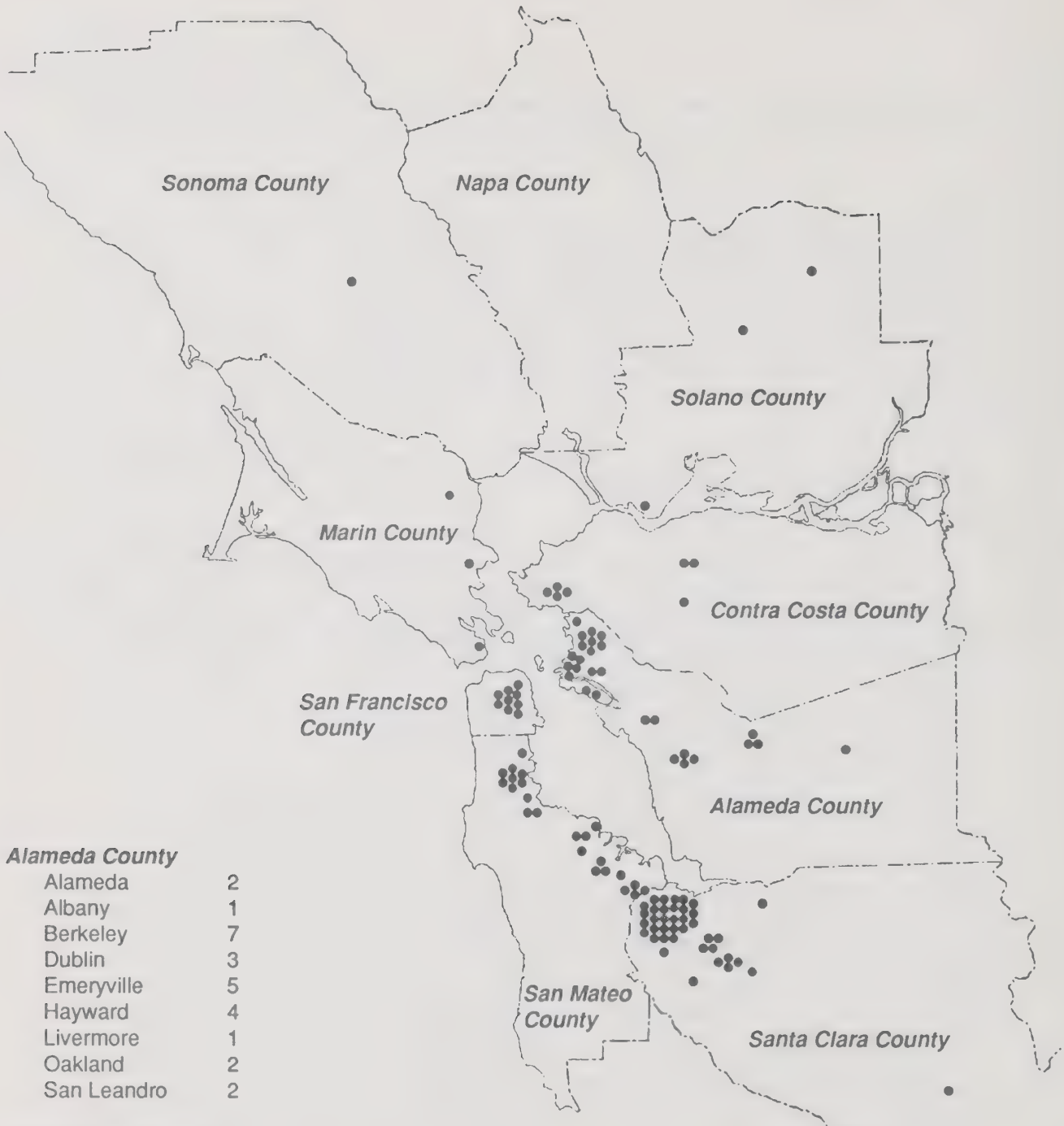
The Bay Area bioindustry is concentrated within Alameda, San Mateo, and Santa Clara counties. By dividing the bioindustry into the biotechnology and the supporting materials technology firms, one can see that most of the materials technology firms (producers of instruments, software, etc.) are located in Santa Clara County and the firms using biotechnology as a production process are concentrated in Alameda and San Mateo Counties. Table 9 shows the concentration of bioindustry firms in the Bay Area in 1987, as identified in Appendix A.

Table 9

Distribution of Bioindustry In the San Francisco Bay Area: 1987*

County	Number of Firms	Percent of Total
Alameda	26	23 %
Contra Costa	8	7 %
Marin	3	3 %
Napa	0	0 %
San Francisco	9	8 %
San Mateo	23	21 %
Santa Clara	39	34 %
Solano	3	3 %
Sonoma	1	1 %
Total Firms	112	

Source: ABAG *The above list is not all-inclusive.



Alameda County	
Alameda	2
Albany	1
Berkeley	7
Dublin	3
Emeryville	5
Hayward	4
Livermore	1
Oakland	2
San Leandro	2

Contra Costa County	
Concord	2
Richmond	4
Walnut Creek	1

Marin County	
Novato	1
San Rafael	1
Sausalito	1

San Francisco County	
San Francisco	9

San Mateo County	
Belmont	1
Brisbane	1
Burlingame	2
Foster City	1
Menlo Park	4
Redwood City	1
San Bruno	1
San Carlos	3
San Mateo	2
South S.F.	7

Santa Clara County	
Cupertino	1
Los Altos	1
Milpitas	1
Morgan Hill	1
Mountain View	12
Palo Alto	14
San Jose	1
Santa Clara	4
Sunnyvale	4

Solano County	
Benicia	1
Dixon	1
Vacaville	1

Sonoma County	
Santa Rosa	1

Location of Bay Area Bioindustry Firms

Source: Association of Bay Area Governments via Bioscan

The concentration of materials technology firms in Santa Clara County is reflective of the development of high tech industries in that part of the region, and the agglomeration economies of locating these types of industries where labor supply and the knowledge base are concentrated.

The distinct locational differences between the materials technology firms and those firms using biotechnology as a production tool is of some importance to those interested in economic development strategies. Two of the older industrial cities in the region, Emeryville and South San Francisco, are home to some of the largest firms using biotechnology, and both communities are centrally located within the region. Of the twenty-three firms in San Mateo County, seven are located in South San Francisco. It is clear that agglomeration economies are underway in that community.

Bioindustry firms are concentrating in Alameda, San Mateo, and Santa Clara counties.

In Alameda County, eleven of the twenty-six firms using biotechnology are located in the Berkeley-Emeryville area. The combination of the traditional industrial areas and the presence of UC Berkeley are factors that should not go unnoticed. It is clear that, in both South San Francisco and Berkeley-Emeryville, traditional industrial areas are evolving into areas of new fast-growing economic activity. These examples are worthy of further analysis with respect to other cities. That is, older communities may have locational and transportation advantages that would permit successful competition with areas where land costs are low and the labor supply is growing. A coordinated regional strategy which looks at all areas would benefit both the industry and economic development within the region.

Local Economic Impacts

Assessing the economic impacts of any industry is not an easy process. The assumptions may change with time and the factors measured may not be the correct variables to analyze. It is beyond the scope of this paper to provide a detailed economic analysis of the Bay Area bioindustry. However, there is sufficient information available to provide a general analysis of the **potential impact of growth in the bioindustry** on other industries in the Bay Area.

National input-output tables are useful since they provide more detail than the 1982 Bay Area Input-Output Table. Input-output tables are accounting instruments that identify which industries provide products to which other industries. The tables also identify industries or consumers who are purchasing the output of an industry.

An input-output table can be used, for example, to identify the major industries that would sell services or products to the industries identified in this study. But, because a national input-output table is used, it may not reflect the actual trading patterns in the Bay Area; in addition, 1982 is the most recent year of published information and purchasing and selling patterns may have changed since that time. Generally, however, these pattern changes are probably slight. Dollar values will not be expressed because of the imprecision of the information, but, a ranking of industries selling products according to the volume of their sales would be a useful comparative analysis.

Wholesale trade firms in the Bay Area are benefiting from increased bioindustry activity.

Table 10

Bay Area Industries Most Benefiting From Growth By Firms Using Biotechnology as a Production Process[4]

Rank	Industry Name
1	Industrial Organic and Inorganic Chemical Firms
2	Wholesale Trade Firms
3	Advertising Firms
4	Instrument Firms
5	Software Engineering Firms
6	Metal Container Firms
7	Building Maintenance Firms
8	Real Estate Firms
9	Agricultural Chemical Firms
10	Plastic Product Firms

Sources: ABAG; 1982 national input-output table.

Table 10 shows the industries that are most affected by the production of firms using biotechnology. A ranking scheme is used which looks at only the top ten industries most affected by firms using biotechnology in their production process. These firms range from chemicals to instruments to building maintenance, and the jobs affected range from blue-collar jobs, such as wholesale trade, to scientific jobs, such as instruments and software engineering, to jobs in advertising. Clearly, there are many more industries affected, but this ranking provides some measure of the impact of these firms on the Bay Area. It is interesting to note the variability in goods produced or services provided by suppliers to this segment of the firms in bioindustry.

Table 11 focuses upon those firms producing instruments and specializing in software engineering for firms using biotechnology. These materials technology firms are serviced by a different group of firms than biotechnology-based firms. The ranking scheme is the same as above, namely a ranking from 1 to 10 with 1 representing the highest dollar volume sales to the firms within the ranking range and 10 representing the least.

Table 11

Bay Area Industries Most Benefiting from Growth of the Materials Technology Firms within Bioindustry[5]

Rank	Industry Name
1	Wholesale Trade
2	Non-Ferrous MetalManufacturing Firms
3	Software engineering, Engineering Services, and Advertising Firms
4	Plastic Product Firms
5	Electronics and Computer Firms
6	Other Instruments Firms
7	Specialized Machine Tools Firms
8	Specialized Ferrous Metal Firms
9	Specialized Fabricated Metal Firms
10	Electrical Equipment Firms

Sources: ABAG; 1982 national input-output table.

Over the long-term, firms with fewer employees will be less likely to survive.

Wholesale trade ranks first as the industry that benefits most from the material technology component of Bay Area bioindustry. Obviously, software engineering, engineering services, and advertising, are major beneficiaries of the growth in firms producing instrumentation for use in biotechnology research and development. Table 11 also suggests that there are greater linkages within manufacturing generally with material technology firms than with firms using biotechnology in the production process.

As previously noted, the nature of production of firms using biotechnology and firms using materials technology differs. Materials technology firms have generally broader markets and produce products that facilitate research and product development in other firms; generally their markets expand because their products serve the needs of other industries. Firms using biotechnology focus on products that will have as their ultimate consumer humans, animals, or crops. This is one reason why firms using biotechnology may not proliferate as rapidly or remain on the competitive market scene as long as firms in the high tech industry.

For example, a simple, and error prone, probability analysis was done on the observed firm size changes in the U.S. pharmaceutical industry over the period 1965-1985. The data are found in County Business Patterns. The analysis suggests that, using the pharmaceutical industry model, firms with fewer than 50 employees have a survival rate of 30 percent or less over a 20-year period. Firms with 50 or more employees have a survival rate of 60 percent or more over 20 years, using the same model. A firm's size, therefore, is an indicator of long-term economic survivability.

Public Policy Implications and Growth Potential

The structure of an economy undergoes continuous change: industries are created, grow, expand, and then decline. Bay Area bioindustry is in its early stages of growth. With respect to assessing its potential, it should be viewed in its segments

rather than as one industry. That is, materials technology firms in the Bay Area bioindustry have as their base the physics and engineering of the computer and electronics industry, and cellular and molecular genetic engineering firms have as their base the chemical and pharmaceutical industries.

The success as major employers of the cellular and molecular genetic engineering firms in the Bay Area and the United States remains uncertain. Genetic engineering technologies have been controversial from the start, and the industry will have to make an effort to achieve greater public acceptance. Ethical, religious, moral, and safety concerns still trouble a segment of the population.

It is uncertain whether cellular and molecular genetic engineering firms will be major Bay Area employers.

These firms, unlike the high tech firms, have more purely market-related problems. Market barriers to entry are high. That is, market obstacles, such as high R & D costs, long-term payback of investments and restrictions to market entry based upon patents, prevent new firms from easily engaging in production. R & D tax credits assist profitable established companies in funding genetic engineering activities, but do little to support start-up companies during their critical years.

And these start-up companies may be the key to U.S. success in competing in a world-wide market. It is important to understand that the cellular and molecular genetic engineering industry is unique with respect to the type and quantity of regulation being imposed upon it. It is one of the few industries which is subject to significant health and safety controls before any hazard has been proved or any industrial accident has occurred.

Given the inherent market constraints on firms using biotechnology as a production tool, as well as the regulatory environment, it is essential that public policy reflect a balance between regulation and the economic development that this industry brings to the Bay Area and the United States.

Recommendations

Consider Economic Benefit as well as Environmental Risks when Regulating Bioindustry

The cellular and molecular engineering firms using biotechnology exist within a highly competitive and speculative market, and economic entry barriers are high for most firms. Given the market conditions, additional obstacles such as confusing and varying regulations among jurisdictions only create more complexity and difficulty for these firms. It is recognized that health and safety concerns should always be paramount in the regulatory framework, and most industries are not adverse to regulation. But a labyrinth of confusing and conflicting regulations affects costs, affects the critical timing of research and development, and reduces ability to supply products in a highly competitive market.

Part of the confusion is unavoidable, given the newness of this industry, but much of it could be minimized by local governments moving toward uniformity in land use and health and safety regulations. Public policy needs to begin to consider more systematically the economic development gains to be realized from a stable and consistent policy process.

Invest in Informing and Educating Bay Area Residents

The industry correspondingly needs to invest more in educating and informing the public and elected officials about the science, regulation, difficulties, hazards, economics, and potential of this industry. One objective of this report is to show its diversity; it is clear that the industry needs to educate others to this diversity. Potential risks need to be discussed along with the industry's record in dealing with this problem. Greater public relations efforts are needed.

Create a Bay Area Bioscience Center

A Bioscience Research Center should be moved from a concept to reality for it would serve to promote the Bay Area as a center of science and technology; it would operate as a source of information about bioindustry, it would encourage debate on issues of health and safety and help to educate the public in these matters; and it would also serve as a research and conference center. In addition, the Center would be expert in public policy with respect to regulation, the science of cellular and molecular engineering, and the engineering and physics of materials technology. In all of its activities, the Center's focus would be on the Bay Area as an economic region, at the same time keeping a national and international perspective.

Conclusions

This research has focused on bioindustry in the Bay Area, a complex and diversified activity. Future employment potential has a large variation based upon the uncertainty of the market place and public policy. The industry clearly offers both redevelopment potential to those areas of the region with a declining industrial base and opportunities for growth in expanding areas of the region.

Afterword

All issues could not be addressed in this chapter, but it will serve as a foundation for future research in the economic development potential of the bioindustry in the Bay Area. This is clearly an exciting industry. Legitimate concerns have been voiced about safety and health hazards in segments of the industry, as well as about the moral question of what type of future we create. Some also oppose this industry for purely anti-science reasons. Unfortunately, this is the environment in which this industry must function. Public policy needs to protect the health and safety of the community, but it also needs to promote economic development opportunities -- a difficult balance, but one that needs to be achieved.

Footnotes

Page 8

1. The low range estimates were based upon linear regression. The upper range reflects exponential regression. The forecast for 1988 was based upon the trend data for 1985-1987. The forecast for 1990 was based upon the trend 1985-1987 and the combined forecasts of data for 1988 and 1989. The year 2000 assumes the existing trend as a linear function of time at the lower end, and an upper range of growth at an increasing rate.

Page 11

2. Firms in sample were: Advanced Polymer Systems, Cetus, Collagen, Genelabs, Genentech, Liposome Technology, Triton Bioscience, Xoma.

Page 14

3. Note: Five or more Bay Area bioindustry firms were engaged in the above research and development efforts in 1987.

Page 20

4. Adjustments were made to national information based upon professional judgment relating to the structure of Bay Area industries. In the ranking scheme 1 = most affected, 10 = least affected.

Page 21

5. Adjustments were made to national information, based upon professional judgment relating to differences between the Bay Area economy and the national economy.

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Alza Corporation, 1985 and 1987.
American Bionetics, Inc., 1987.
Applied Biosystems, Inc., 1986 and 1987.

Becton Dickinson and Company, 1987.
Bio-Rad Laboratories, Inc.,1985 and 1986.
Bio Response, Inc., 1985 and 1986.

California Biotechnology, Inc., 1985 and 1986.
Cetus Corporation, 1986 and 1987.
Chevron Corporation, 1986.
Chiron Corporation, 1986 and 1987.
Calgene, 1986 and 1987.
CooperVision, Inc., 1986.
Cooper Companies, Inc., 1987.
Cooper Development Company, 1986 and 1987.
Cooper LaserSonics, Inc., 1986 and 1987.
Collagen Corporation, 1986 and 1987.

Diasonics, 1985 and 1986.

Escagen (IPRI), 1987.

Genetech, Inc., 1985 and 1986.

Hana Biologics, Inc., 1987.
Hewlett-Packard, 1987.

Imatron, Inc., 1985 and 1986.

Lipsome Technology, 1987.

Miles Laboratories, Inc. (Cutter Labs), 1986.
Monoclonal Antibodies, Inc., 1986 and 1987.

Monoclonal Antibodies, Inc., 1987.

Nellcor, Inc., 1987.
New Brunswick Scientific Co. (Biosearch),1986.

Syntex Corporation, 1986 and 1987.

Three M, 1985 and 1986.

Xoma Corporation, 1986 and 1987.

Other References

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BioTech 88: Into The Market Place. A survey of an industry in evolution, including interviews with key industry leaders. Arthur Young High Technology Group, Arthur Young International, 1987.

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Business Prospector: Business Reference Directory, Oakland Metro. Business Prospector, San Mateo, 1987.

Business Prospector: Business Reference Directory, Peninsula. Business Prospector, San Mateo, 1986.

Business Prospector: Business Reference Directory, San Francisco. Business Prospector, San Mateo, 1987.

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The Disclosure Information Group, Bethesda, 1987.

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San Mateo County Commerce and Industry Directory. BIS, Inc., San Mateo, 1985.

Santa Clara County Commerce and Industry Directory., BIS, Inc., San Mateo, 1986.

San Francisco Bay Area Bioindustry Firms as of 1987

Alameda County

Advanced Genetics Research Inst.
2220 Livingston St.
Oakland 94606

Advanced Genetic Sciences
6701 San Pablo Ave.
Oakland 94608

American Bionetics
21377 Cavot Blvd.
Hayward 94545

Berkeley Antibody Co.
4131 Lakeside Dr. Ste. B
Berkeley 94806

Biogenex Laboratories
6549 Sierra Lane
Dublin 94568

Biolog
——
Hayward ——

Bio-Response, Inc.
1978 W. Winton Avenue
Hayward 94545

California Integrated Diagnostics
1440 Fourth St.
Berkeley 94710

Cetus Corp
1400 53rd St.
Emeryville 94608

Chiron Corporation
4560 Horton
Emeryville 94608

Cutter Laboratories
P.O. Box 1986
Berkeley 94701

Enzyme Systems Products
6497 Sierra Lane
Dublin 94568

Hana Biologics, Inc.
850 Marina Village Prkwy.
Alameda 94501

Hytech Biomedica, Inc.
1440 Fourth St.
Berkeley 94703

Lucky Biotech Corp.
4560 Horton St.
Emeryville 94608

Medi-Physics
9855 Christie Ave.
Emeryville 94608

Mitech
——
Berkeley ——

Molecular Design
——
San Leandro 94578

—— = Information not located when research was conducted.

Alameda County (continued)	*Contra Costa County*
Nellcor 25495 Whitesell St. Hayward 94545	Aqua Genetics —— Walnut Creek ——
Northview Pacific Laboratories 2800 Seventh St. Berkeley 94710	Biogrowth, Inc. 3065 Atlas Rd. Suite 117 Richmond 94806
Plant Cell Research Institute —— Dublin 94568	Bio-Rad Laboratories, Inc. 2200 Wright Ave. Richmond 94804
Plant Gene Expression Center 800 Buchanan St. Albany 94710	Microgenics Corporation —— Concord ——
Research and Diagnostic Antibodies 6450 Bay St. Emeryville 94608	Siemens Medical Labs —— Concord ——
Sepragen Corporation 2126 Edison Ave. San Leandro 94577	Stauffer Chemical Co. —— Richmond ——
SETEC, Inc. P.O. Box 3002 Livermore 94550	Tissue-Grown Corporation 6822 Del Monte Ave. Richmond 94805
Triton Biosciences, Inc. 1501 Harbor Bay Parkway Alameda 94501	
XOMA Corporation 2910 Seventh St. Berkeley 94710	

Marin County	*San Francisco County (continued)*
Biosearch 2980 Kerner Blvd. San Rafael 94901 Earl-Clay laboratories, Inc. 890 Lamont Ave. Novato 94945 Gametrics, Ltd. 475 Gate Rd. Ste. 308 Sausalito 94966	Kikkoman Corp. (Japan) 50 California St. Ste. 3600 San Francisco 94111 Locus Biosystems 2001 Broadway Suite 404 San Francisco 94115 Replicon Laboratories P.O. Box 27053 San Francisco 94127
San Francisco County	***San Mateo County***
Advanced Biotechnology Assoc. 77 Post St. Suite 700 San Francisco 94108 Bechtel Group Beach St. San Francisco —— Bioaccess, Inc. 55 Java St. San Francisco 94227 Chevron Chemical Co. —— San Francisco —— Crown Zellerbach —— San Francisco —— Cyto Culture International Inc. 1208 4th Avenue San Francisco 94122	Applied Biosystems, Inc. 850 Lincoln Center Dr. Foster City 94404 Applied Immune Systems, Inc. —— Menlo Park —— Bio-Genetics —— So. San Francisco —— Codon 430 Valley Dr. Brisbane 94005 Cooper Development Co. 75 Willow Rd. Menlo Park 94025 Creative Biomolecules 385 Oyster Point Blvd. So.SanFrancisco 94080

San Mateo County (continued)

Engenics, Inc.
3760 Haven Ave.
Menlo Park 94025

Escagen Corp.
830 Bransten Rd.
San Carlos 94070

E-Y Laboratories, Inc.
107 North Amphlett Blvd.
San Mateo 94401

Genelabs, Inc.
505 Penobscot Dr.
Redwood City 94063

Genencor, Inc.
180 Kimball Way
So.San Francisc 94402

Genentech, Inc.
460 Point San Bruno Blvd.
So.SanFrancisco 94080

IDETEK, Inc.
1057 Smeath Lane
San Bruno 94066

Imatron, Inc.
389 Oyster Point
So.SanFrancisco 94080

Immunovet
——
So. San Francisco ——

IPRI
——
San Carlos ——

Liposome Technology, Inc.
1050 Hamilton Court
Menlo Park 94025

N.I.E. Plant Tissue Laboratory
529 East 3rd St.
San Mateo 94401

Peninsula Laboratories, Inc.
611 Taylor Way
Belmont 94022

TAGO
——
Burlingame ——

Vector Laboratories
1429 Rollins Road
Burlingame 94101

Wedgwood Technologies, Inc.
100 Industrial Way
San Carlos 94070

Zymed Laboratories
52 South Linden Ave. Ste. E
So.San Francisco 94080

Santa Clara County

3-M Diagnostics
3380 Central Expressway
Santa Clara 95051

Santa Clara Acuson
1220 Charleston Road,
Mountain View 94039

AGEN USA, Inc.
110 Pioneer Wy, Ste. A
Mountain View 94043

Alza Corporation
950 Page Mill Rd.
Palo Alto 94303

Astra Scientific, Inc
1961 Concourse Dr.
San Jose 95131

Becton Dickinson Monoclonal Ctr.
2375 Garcia Ave.
Mountain View 94043

Biosis
1057 E. Meadow Circle
Palo Alto 94606

Biotherapy Systems, Inc.
——
Mountain View ——

California Biotechnology, Inc.
2450 Bayshore Parkway
Mountain View 94043

Carvo Scientific Instruments
242 Humboldt Court
Sunnyvale 94089

Clontech Laboratories, Inc.
4055 Fabian Way
Palo Alto 94303

Collagen Corp.
2500 Faber Place
Palo Alto 94303

DDI Pharmaceuticals, Inc.
518 Logue Avenue
Mountain View 94043

Diasonics
1656 McCarty Blvd.
Milpitas 95035

Dionex Corporation
1228 Titan Way
Sunnyvale 94088

DNAX Research Institute
1450 Page Mill Rd.
Palo Alto 94304

Dohrmann/Rosemount Analytical
3240 Scott Blvd.
Santa Clara 95054

EAN-TECH, Inc.
325 East Middlefield Rd.
Mountain View 94043

Santa Clara County (continued)

Fermentec Corporation
101 First St. Suite 490
Los Altos 94022

Hewlett-Packard
3000 Hanover St.
Palo Alto 94304

Hitachi Instruments
——
Santa Clara ——

Holtz Bio-Engineering
——
Morgan Hill ——

IDEC, Inc.
291 North Bernardo Ave.
Mountain View 94043

Intelligenetics
124 University Ave.
Palo Alto 94301

Laserscope
3350 Scott Blvd.
Santa Clara 95054

Mast Immunosystems, Inc.
630 Clyde Court
Mountain View 94043

Monoclonal Antibodies, Inc.
2319 Charleston Rd.
Mountain View 94943

Nelson Analytical
10061 Bubb Road
Cupertino ——

Neurex Corporation
1500 Salado Dr.
Mountain View 94043

Protein Design Labs
3181 Porter Dr.
Palo Alto 94304

Salutar, Inc.
428 Oakmead Parkway
Sunnyvale 94086

Sandoz Corporation
975 California Ave.
Palo Alto 94304

SENETEK PLC
444 Castro St. Ste. 710
Mountain View 94041

Smith-Kline
485 Potero Ave.
Sunnyvale 94086

Sungene Technologies Corp.
3330 Hillview Ave.
Palo Alto 94304

Syntex
3401 Hillview Avenue
Palo Alto 94304

Santa Clara County (continued)	
Syva Co. —— Palo Alto	——
Varian 611 Hansen Way Palo Alto	94303
Zoecon Corporation 975 California Ave. Palo Alto	94304
Solano County	
Infergene Company 433 Industrial Way Benicia	94510
Biosource 3333 Vaca Valley Parkway Vacaville	95688
Hemostat Laboratories 120 North Jackson Dixon	95620
Sonoma County	
Henkel Research Corp. —— Santa Rosa	——

—— = Information not located when research was conducted.

Sources: ABAG; Annual Reports

Brief Information on Selected Bioindustry Companies in the San Francisco Bay Area,1987

Company Name	Description	Founded
Alameda County		
Advanced Genetics Research Inst.	Subsidiary of Agrion Company	1980
Advanced Genetic Sciences	——	1979
American Bionetics	——	1981
Berkeley Antibody Co.	Not listed in Bioscan Directory	——
Biogenex Laboratories	——	1981
Biolog	——	——
Bio-Response, Inc.	——	1972
California Integrated Diagnostics	Not listed in Bioscan Directory	——
Cetus Corp.	Cetus Immune Division in Palo Alto. European subsid. EuroCetus - for clinical trials and marketing	1971
Chiron Corporation	——	1981
Cutter Laboratories	Not listed in Bioscan Directory	——
Enzyme Systems Products	——	1980
Hana Biologics, Inc.	Not listed in Bioscan Directory	1979
Hytech Biomedical, Inc.	Not listed in Bioscan Directory	——
Lucky Biotech Corp.	Company based in Korea	——
Medi-Physics	——	——
Mitech	Focus: fungal pesticides	1984
Molecular Design	Focus: chemical information & research software programming	——
Northview Pacific Laboratories	Not listed in Bioscan Directory	——
Plant Cell Research Institute	Subsidiary of ARCO	1981
Research and Diagnostic Antibodies	Not listed in Bioscan Directory	——
Sepragen Corporation	Not listed in Bioscan Directory	——
SETEC, Inc.	Not listed in Bioscan Directory	——
Triton Biosciences, Inc.	——	1983
XOMA Corporation	——	——

Company Name	Description	Founded
Contra Costa County		
Aqua Genetics	Conducts research on marine organism genetic modification	1981
Biogrowth, Inc.	Not listed in Bioscan Directory	——
Bio-Rad Laboratories, Inc.	——	1957
Microgenics Corporation	——	1981
Plant Gene Expression Center	Not listed in Bioscan Directory	——
Stauffer Chemical Co.	——	——
Tissue-Grown Corporation	Not listed in Bioscan Directory	1976
Marin County		
Biosearch	Subsid. of New Brunswick Scientific	1976
Earl-Clay laboratories, Inc.	Not listed in Bioscan Directory	——
Gametrics, Ltd.	——	1974
San Francisco County		
Advanced Biotechnology Assoc.	——	1981
Bechtel Group	Subsid. of Bechtel Corp.	——
Bioaccess, Inc.	Not listed in Bioscan Directory	——
Chevron Chemical Co.	Subsid. of Chevron Corp. w/ farm research facility in Fairfield.	——
Crown Zellerbach	——	——
Cyto Culture International, Inc.	Not listed in Bioscan Directory.	——
Kikkoman Corp. (Japan)	——	——
Locus Biosystems	Not listed in Bioscan Directory.	——
Replicon Laboratories	——	1981

Company Name	Description	Founded
San Mateo County		
Applied Biosystems, Inc.	Has facility in West Germany. Subsid. Brownlee Labs, Inc., Santa Clara, 40% foreign sales.	1981
Applied Immune Systems, Inc.	——	——
Bio-Genetics	Sperm separation and embryo transfer in animal genetics.	1973
Codon	——	1980
Cooper Development Co.	——	1980
Creative Biomolecules	——	1981
Engenics, Inc.	——	1981
Escagen Corp.	——	——
E-Y Laboratories, Inc.	——	1978
Genelabs, Inc.	Research and development is biotechnology based human health care products.	1984
Genencor, Inc.	——	1982
Genentech, Inc.	——	1976
DETEK, Inc.	Not listed in Bioscan Directory.	——
Immunovet	——	——
Liposome Technology, Inc.	——	1981
N.I.E. Plant Tissue Laboratory	——	1979
Peninsula Laboratories, Inc.	——	1971
TAGO	——	1971
Vector Laboratories	Not listed in Bioscan Directory	——
Wedgwood Technologies, Inc.	Not listed in Bioscan Directory	——
Zymed Laboratories	——	——

Company Name	Description	Founded
Santa Clara County		
3-M Diagnostics	——	——
AGEN USA, Inc.	——	——
Alza Corporation	——	1968
Astra Scientific, Inc.	Not listed in Bioscan Directory	——
Becton Dickinson Monoclonal Ctr.	Subsid., Becton Dickinson, N.J.	——
Biosis	——	1983
Biotherapy Systems, Inc.	——	——
California Biotechnology, Inc.	——	1981
Clontech Laboratories, Inc.	——	1984
Collagen Corp.	——	1975
DDI Pharmaceuticals, Inc.	——	1965
Dionex Corporation	Not listed in Bioscan Directory	——
DNAX Research Institute	——	1980
Dohrmann/Rosemount Analytical Div.	Not listed in Bioscan Directory	——
EAN-TECH, Inc.	Not listed in Bioscan Directory	——
Fermentec Corporation	Not listed in Bioscan Directory	——
Holtz Bio-Engineering	Fermentation & process pilot	——
DEC, Inc.	Not listed in Bioscan Directory	——
Intelligenetics	——	1980
Mast Immunosystems, Inc.	Not listed in BioScan Directory	——
Monoclonal Antibodies, Inc.	——	——
Neurex Corporation	Not listed in Bioscan Directory	——
Protein Design Labs	Not listed in Bioscan Directory	——
Salutar, Inc.	Not listed in Bioscan Directory	——
Sandoz Corporation	Not listed in Bioscan Directory	——
SENETEK PLC	Not listed in Bioscan Directory	——
Sungene Technologies Corp.	——	1981
Syntex	——	1944
Syva Co.	——	1977
Varian	——	——
Zoecon Corporation	——	1968

Company Name	Description	Founded
Solano County		
Infergene Company	Not listed in Bioscan Directory.	——
Sonoma County		
Henkel Research Corp.	——	1985

Sources: ABAG; Bioscan: The Biotechnology Corporate Directory, 1987.

Brief History and Financial Status of Selected Bioindustry Firms, 1987

Company Name	History	Financial Status
Alameda County		
Advanced Genetics Research Inst.	—	Private
Advanced Genetic Sciences	Closed Kansas facility to concentrate in R&D in Berkeley (7/84)	Public
American Bionetics	Formerly American Bionuclear	—
Berkeley Antibody Co.	—	—
Biogenex Laboratories	—	Private
Biolog	—	Private
Bio-Response, Inc.	—	Public
California Integrated Diagnostics	—	—
Cetus Corp	Contract research completed 1971-85 for Schering-Plough, Ruosell Uclaf, Chevron, National Distillers, Imperial Chemical Industries, Norden, TechAmerica	Public
Chiron Corporation	—	Public
Cutter Laboratories	—	Public
Enzyme Systems Products	Relocated in Bay Area.	—
Hana Biologics, Inc.	—	Public
Hytech Biomedical, Inc.	—	—
Lucky Biotech Corp.	—	—
Medi-Physics	—	—
Mitech	—	—
Molecular Design	—	Private
Northview Pacific Laboratories	—	—
Plant Cell Research Institute	—	—
Research & Diagnostic Antibodies	—	—
Sepragen Corporation	—	—
SETEC, Inc.	—	—
Triton Biosciences, Inc.	Previously Applied BioSciences Subsid. of Shell Oil	—
XOMA Corporation	—	Public

Company Name	History	Financial Status
Contra Costa County		
Aqua Genetics	owns Ocean Genetics (Tiburon)	—
Biogrowth, Inc.	—	—
Bio-Rad Laboratories, Inc.	Founded by D. Schwartz,et al. 58% owned	Public
Microgenics Corporation	—	Private
Plant Gene Expression Center	—	—
Stauffer Chemical Co.	—	—
Tissue-Grown Corporation	—	—
Marin County		
Biosearch	Biotech research began 1980.	Public
Earl-Clay Laboratories, Inc.	—	—
Gametrics, Ltd.	—	Private
San Francisco County		
Advanced Biotechnology Assoc.	—	Private
Bechtel Group	—	—
Bioaccess, Inc.	—	—
Chevron Chemical Co.	—	Public
Crown Zellerbach	—	—
Cyto Culture International, Inc.	—	—
Kikkoman Corp. (Japan)	—	—
Locus Biosystems	—	—
Replicon Laboratories	—	Private
San Mateo County		
Applied Biosystems, Inc.	—	Public
Applied Immune Systems, Inc.	—	Private
Bio-Genetics	—	Private
Codon	UCSF researchers founded with venture partnership	Private

Company Name	History	Financial Status
Cooper Development Co.	Originally a parent co. named Cooper Labs, with several divisions, one of which was CooperBiomedical. Cooper Labs dissolved in '85. In '86 became Cooper Develop. Co.	Public
Creative Biomolecules	—	Private
Engenics, Inc.	Founded by former faculty from Stanford and UCB	Private
Escagen Corp.	—	Public
E-Y Laboratories, Inc.	—	Private
Genelabs, Inc.	Moved facilities from San Carlos to Redwood City in 1986	Private
Genencor, Inc.	Joint venture between Genentech and Corning (1982), each company to invest $40 million between 1982 & 1987	
Genentech, Inc.	—	Public
IDETEK, Inc.	—	—
Immunovet	—	—
Liposome Technology, Inc.	—	Public
N.I.E. Plant Tissue Laboratory	—	Private
Peninsula Laboratories, Inc.	—	Private
TAGO	—	Public
Vector Laboratories	—	—
Wedgwood Technologies, Inc.	—	—
Zymed Laboratories	—	—
Santa Clara County		
3-M Diagnostics	—	Public
AGEN USA, Inc.	—	Private
Alza Corporation	Ciba-Geigy in 1982 divested controlling interest in Alza	Public
Astra Scientific, Inc.	—	—
Becton Dickinson Monoclonal Ctr.	—	Public

Company Name	History	Financial Status
Biosis	Founder - Bernard Oliver from Hewlett-Packard	—
Biotherapy Systems, Inc.	—	Public
California Biotechnology, Inc.	Organized with $5mil in private funding.	Public
Clontech Laboratories, Inc.	—	Private
Collagen Corp.	230 employees (1986)	Public
DDI Pharmataceticals, Inc.	48 employees (1987)	Public
Dionex Corporation	—	—
DNAX Research Institute	65 scientists employed in 7/85	Public
Dohrmann/Rosemount Analytical Div.	—	Public
EAN-TECH, Inc.	—	—
Fermentec Corporation	—	—
Holtz Bio-Engineering	—	Private
IDEC, Inc.	—	—
Intelligenetics	Founded by former faculty of Stanford.	Public
Mast Immunosystems, Inc.	—	—
Monoclonal Antibodies, Inc.	—	Public
Neurex Corporation	—	—
Protein Design Labs	—	—
Salutar, Inc.	—	—
Sandoz Corporation	—	—
SENETEK PLC	—	—
Sungene Technologies Corp.	—	Private
Syntex	—	Public
Syva Co.	Subsid. of Syntex	—
Varian	—	Public
Zoecon Corporation	Subsid. of Sandoz	—
Solano County		
Infergene Company	—	—
Sonoma County		
Henkel Research Corp.	Established to develop products using genetic engineering techniques (1985)	—

Sources: ABAG, Bioscan: The Biotechnology Corporate Directory Service, 1987.

Employment and Operating Statistics of San Francisco Bay Area Bioindustry Firms

Name	1987 SIC	Years	Em-ploy.	Revenue (millions)	Net Income (millions)	Plant& Equip. (millions)	Capital Expend. (millions)
Alameda County							
Advanced Genetic Sciences	8731	*1987	112	----	----	----	----
		*1986	99	----	----	----	----
		1985	93	----	-8.200	----	----
Bio-Response, Inc	2835	*1987	86	----	----	----	----
		1986	75	0.667	-5.859	4.269	0.401
		1985	68	2.476	-3.779	4.568	0.958
Cetus Corp	8731	1987	730	43.900	-9.200	39.227	8.336
		1986	640	39.595	1.097	36.294	3.670
		1985	600	45.365	1.225	38.314	5.603
Chiron Corp	8731	1987	263	10.503	-7.318	10.418	6.458
		1986	162	7.134	-4.160	5.528	1.974
		1985	144	5.886	-2.241	4.573	2.896
Cutter Labs	2834	*1987	805	----	----	----	----
		1986	800	84.800	----	----	----
		1985	785	81.500	----	----	----
Hana Biologics, Inc	2835	1987	151	4.297	-1.175	5.366	4.911
		1986	126	3.536	0.070	0.992	0.704
		1985	91	3.196	-0.857	0.683	0.264
Nellcor Inc	3841	1987	600	81.040	8.923	9.005	7.068
		1986	420	46.167	9.578	4.796	3.928
		1985	180	13.157	-0.759	----	1.695
Plant Cell Research Institute	2879	*1987	135	----	----	----	----
		*1986	100	----	----	----	----
		*1985	93	----	----	----	----

* = Data were estimated. Note: No data or incomplete data = ----

Name	1987 SIC	Years	Em-ploy.	Revenue (millions)	Net Income (millions)	Plant& Equip. (millions)	Capital Expend. (millions)
Triton Biosciences, Inc	8731	1987	181	----	----	----	----
		1986	140	----	----	----	----
		*1985	120	----	----	----	----
XOMA Corp	8731	1987	160	5.800	-12.800	3.500	----
		1986	150	0.110	-46.652	4.538	1.623
		1985	145	7.700	-4.828	5.742	2.666
Siemens Med Labs, Inc	3841	*1987	75	----	----	----	----
		*1986	50	----	----	----	----
		*1985	45	----	----	----	----
Contra Costa County							
Bio-Rad Labs, Inc	3826	*1987	1480	----	----	----	----
		1986	1300	126.579	5.774	33.904	22.857
		1985	1100	102.329	4.252	13.785	8.048
Chevron Chemical	2879	*1987	399	----	----	----	----
		1986	350	----	----	----	----
		1985	325	----	----	----	----
Microgenics	8733	1987	85	----	----	----	----
		1986	45	----	----	----	----
		1985	20	----	----	----	----
Marin County							
Biosearch	3829	*1987	100	----	----	----	----
		1986	50	31.515	1.474	5.351	0.896
		*1985	40	26.550	0.728	5.405	2.010

* = Data were estimated.

Note: No data or incomplete data = ----

Name	1987 SIC	Years	Em-ploy.	Revenue (millions)	Net Income (millions)	Plant& Equip. (millions)	Capital Expend. (millions)
San Francisco County							
Stauffer Chemical Company	2879	*1987	425	----	----	----	----
		1986	400	----	----	----	----
		1985	410	----	----	----	----
San Mateo County							
Advanced Polymer Systems	8731	*1987	65	----	----	----	----
		1986	40	0.326	-2.211	*3.646	3.129
		1985	38	0.236	-1.548	0.638	0.420
Applied Biosystems, Inc	3826	1987	788	107.700	12.000	12.867	4.586
		1986	465	51.748	10.367	9.763	7.725
		1985	275	35.563	6.929	3.609	2.714
Codon	8731	1987	120	----	----	----	----
		*1986	108	----	----	----	----
		*1985	83	----	----	----	----
Diasonics	3826	*1987	1577	----	----	----	----
		1986	1383	217.124	-16.701	14.996	7.934
		1985	1248	156.443	7.065	13.935	2.567
Genencor Inc	8731	*1987	125	----	----	----	----
		1986	100	----	----	----	----
		*1985	89	----	----	----	----
Genentech, Inc	2836	*1987	1968	----	218.900	42.200	----
		1986	1168	133.900	-352.204	133.12	52.246
		1985	893	89.600	5.608	87.924	20.247
Imatron Inc	3826	*1987	55	----	----	----	----
		1986	41	3.599	-7.977	3.776	1.104
		1985	38	2.391	-6.005	3.602	1.142

* = Data were estimated.

Note: No data or incomplete data = ----

Name	1987 SIC	Years	Em-ploy.	Revenue (millions)	Net Income (millions)	Plant& Equip. (millions)	Capital Expend. (millions)
PRI Inc	8731	*1987	55	----	----	----	----
		1986	48	2.791	-0.414	0.482	----
		1985	40	2.348	-0.699	----	----
Liposome Technology Inc	8731	1987	83	4.283	2.082	1.345	0.372
		1986	65	3.575	-1.291	0.973	0.261
		1985	51	2.729	-0.441	0.934	0.569
Applied Immune Systems,Inc.	2834	1987	90	----	----	----	----
		*1986	81	----	----	----	----
		*1985	62	----	----	----	----
Peninsula Labs, Inc	2835	1987	50	----	----	----	----
		*1986	41	----	----	----	----
		*1985	40	----	----	----	----
Santa Clara County							
Acuson Computed Sonography	3826	*1987	410	----	----	----	----
		1986	389	64.100	11.239	7.941	5.116
		1985	299	31.300	3.756	4.889	3.370
ALZA Corp	8731	1987	500	----	----	----	----
		1986	422	15.886	16.753	37.115	17.966
		1985	396	15.139	9.707	21.132	6.387
Becton Dickinson Monoclonal	3826	1987	300	24.600	2.308	754.872	190.968
		1986	253	----	----	----	----
		1985	200	----	----	----	----
California Biotechnology, Inc.	8731	*1987	215	----	----	----	----
		1986	162	9.439	-18.968	29.329	26.144
		1985	108	7.548	-0.454	4.604	1.599

* = Data were estimated.

Note: No data or incomplete data = ----

Name	1987 SIC	Years	Em-ploy.	Revenue (millions)	Net Income (millions)	Plant& Equip. (millions)	Capital Expend. (millions)
Collagen Corp	2835	1987	235	22.172	1.679	5.307	1.051
		1986	208	20.072	1.800	5.616	0.742
		1985	225	16.425	0.965	6.021	1.398
Cooper Development	8731	1987	85	----	53.591	2.568	1.351
		1986	50	----	-61.670	1.564	1.029
		1985	31	2.507	-10.040	1.198	0.360
Cooper LaserSonics, Inc	3826	1987	660	64.565	-12.500	6.381	1.165
		1986	690	68.055	-5.200	8.754	1.501
		1985	600	63.843	0.500	8.858	3.346
DNAX Research Inst	2836	*1987	80	----	----	----	----
		*1986	65	----	----	----	----
		*1985	50	----	----	----	----
Hewlett-Packard	3826	1987	675	24.643	2.308	11.75	2.974
		*1986	600	----	----	----	----
		*1985	590	----	----	----	----
Hitachi Instruments Inc	7372	1987	81	----	----	----	----
		1986	63	----	----	----	----
		1985	60	----	----	----	----
Laserscope	3826	*1987	89	----	----	----	----
		1986	59	----	----	----	----
		*1985	51	----	----	----	----
Monoclonal Antibodies, Inc	2833	1987	139	6.227	-8.079	2.239	1.384
		1986	112	7.666	-0.074	1.312	0.251
		1985	102	3.830	-2.870	1.574	0.453
Nelson Analytical Inc	7372	*1987	70	----	----	----	----
		1986	63	----	----	----	----
		*1985	50	----	----	----	----

* = Data were estimated.

Note: No data or incomplete data = ----

Name	1987 SIC	Years	Em-ploy.	Revenue (millions)	Net Income (millions)	Plant& Equip. (millions)	Capital Expend. (millions)
Resonex	3841	*1987	89	----	----	----	----
		1986	71	----	----	----	----
		*1985	60	----	----	----	----
Syntex	2834	1987	3300	400.700	88.20	138.900	29.900
		1986	3264	347.700	70.50	124.500	20.300
		1985	3193	301.400	53.20	120.800	17.900
Syva Company	3829	*1987	1273	----	----	----	----
		1986	1200	89.200	----	----	----
		*1985	1151	----	----	----	----
3-M Diagnostics	2835	1987	152	----	----	----	----
		1986	135	12.400	----	----	----
		1985	120	10.300	----	----	----
Zoecon Corp	2879	*1987	290	----	----	----	----
		1986	280	----	----	----	----
		*1985	250	----	----	----	----
Henkel Research Group	2833	1987	90	----	----	----	----
		*1986	60	----	----	----	----
		*1985	43	----	----	----	----

Total Bay Area Bioindustry Employment

1987	19,421
1986	16,543
1985	14,650

Sources: ABAG; Company financial reports;
Bioscan: The Biotechnology Corporate Directory, 1987.

* = Data were estimated. Note: No data or incomplete data = ----

Links Between Bay Area Biotechnology Firms and Multi-National Corporations

Company	Involvement	Multi-National Corporation
Alza Corp.		
	Agreements	Ciba-Geigy
Becton Dickinson Monoclonal		
	Subsidiary	Becton Dickinson Corp.
Biosearch		
	Subsidiary	New Brunswick Scientific
California Biotechnology		
	Develop. & Mrktng Agrmnt.	Eli Lilly
	Preclinical Evaluation Agrmnt	Hoffmann-La Roche
	Licensing Agreement	US Dept. of Commerce
Cetus Corporation		
	Joint Venture called Agricetus	W.R. Grace
	Development Partnership	Perkin-Elmer
	Joint Venture	Nabisco
	Evaluation Agreement	Schering AG
Chevron Chemical Co.		
	Subsidiary	Chevron Corp.
Chiron Corporation		
	Licensing Agreement	Hoechst
	Joint Venture & R&D	Ciba-Geigy
	Research and Supply Agreement	Johnson & Johnson

Company	Involvement	Multi-National Corporation
Codon Corp.		
	Agreement	McDonnell Douglas
Collagen Corp.		
	Joint Venture	Eli Lilly
	Marketing Agreement	Schering-Plough
	Devel. & Distrib. Agreement	Bristol-Meyers
Cooper Development Co.		
	Licensing Agreement	National Found. for Cancer
Cutter Laboratories		
	Subsidiary	Miles Laboratories
Dnax Research Institute		
	Major Stock Holder - 80%	Schering-Plough
Dohrmann/Rosemount Analytical		
	Subsidiary	Dohrmann/Rosemount
Escagen Corp.		
	Development Agreement	Anheuser-Busch
	Development Agreement	General Foods
	Development Agreement	Del Monte
Genelabs, Inc.		
	Primary Investor	Syntex
Genencor, Inc.		
	Subsidiary	A.E. Staley

Company	Involvement	Multi-National Corporation
Genentech, Inc.		
	Supply Agreement	Alfa-Laval
	Devel. & Distribute	Bayer
	Joint Venture & Market	Boehringer Ingelheim
	Rights & Royalty Agreement	Ciba-Geigy
	Joint Venture	Corning, A.E. Staley
	Development & Marketing	Hoffmann-La Roche
	Joint Venture	Lubrizol, Pfizer
		National Institutes of Health
Hana Biologics, Inc.		
	Distribution Agreement	Dupont
Plant Cell Research Instit.		
	Subsidiary	ARCO
Syntex		
	Royalty Agreement	Eli Lilly
Syva Corp.		
	Subsidiary	Syntex
Triton Biosciences, Inc.		
	Subsidiary	Shell Oil
Xoma Corporation		
	Licensing Agreement	Hoffmann-La Roche
	Development & Marketing	Pfizer

Sources: ABAG; Bioscan: The Biotechnology Corporate Directory Service, The Oryx Press, Phoenix, 1987.

Research Biocodes and Contract Agreements Between Bay Area Bioindustry Firms and Other Firms

City	Company Name	Agreements	Biocodes
Alameda County			
Hayward	Bio-Response	2	503,511,201 400
Emeryville	Cetus Corporation	15	511,501,516 509,517,518 510,401,406 414,412,403 413,107,109 606,607,303 214,209
Emeryville	Chiron Corporation	20	518,512,510 508,515,509 503,513,412 401,410,406 414,107,607 604,302,205 208
Berkeley	Cutter Laboratories	unk.	503
Alameda	Hana Biologics, Inc.	1	500,400
Alameda	Triton Biosciences, Inc.	3	501,509,510 403,404,209
Oakland	Advanced Genetic Sciences	unk.	111,102,109 104,107,302
Berkeley	XOMA Corporation	10	501,511,517 403,412,413 414

City	Company Name	Agreements	Biocodes
Contra Costa County			
Richmond	Bio-Rad Laboratories, Inc.	unk.	401,404,408 412,212,206 213
Concord	Micorgenics Corporation	1	407,408,412 414,508
Richmond	Stauffer Chemical	unk.	101
Marin County			
San Rafael	Biosearch	3	206,212
San Francisco County			
San Francisco	Chevron Chemical Company	unk.	102,105,109 203,211
San Mateo County			
Menlo Park	Cooper Development Company	10*	502,506,510
Brisbane	Codon Corporation	2	508,406,512 607,302,201 208,212
Redwood City	Genelabs, Inc.	unk.	412,510
South San Francisco	Genencor, Inc.	3	302,301,208 214,209,215
Menlo Park	Liposome Technology, Inc.	unk.	505,506

City	Company name	Agreements	Biocodes
South San Francisco	Genentech, Inc.	53 (1986)	505,510,512 516,507,503 509,515,508 502,518,501 401,106,108 606,607,604 302,207,203 209
San Carlos	Escagen Corporation	10	103,104,107 110
Belmont	Peninsula Laboratories, Inc.	unk.	412
Foster City	Applied Biosystems, Inc.	unk.	404,209,212 206,213
Menlo Park	Applied Immune Systems, Inc.	unk.	501,510,514
Santa Clara County			
Mountain View	Becton Dickinson Monoclonal Center	unk.	209,400
Palo Alto	Syva Corporation	1	412,414,407 405,209
Santa Clara	3-M Diagnostics	unk.	209,402
Palo Alto	Alza Corporation	12	505,516,606
Palo Alto	Collagen Corporation	6 (1986) 8 (1987)	505,506,508
Palo Alto	Syntex	8	501,509,518 402,403,408 411,412,413 414,604,607 103,209

City	Company Name	Agreements	Biocodes
Santa Clara	Dohrmann/Rosemount Analytical Div.	unk.	103, 209
Palo Alto	Zoecon Corporation	2	102,110,107 106,104,111 605,207
Mountain View	California Biotechnology	20	504,512,508 513,505,507 509,510,402 409,406,608 606
Palo Alto	Dnax Research Institute	unk.	201,504,510
Mountain View	Monoclonal Antibodies	6	408,412,601 603
Palo Alto	Sungene Technologies Corporation	2	101,107
Palo Alto	Varian	unk.	209,405
Sonoma County			
Santa Rosa	Henkel Research Group	unk.	214

Sources: Bioscan: The Biotechnology Corporate Directory Service, 1987; Various news articles in Pharma Projects.

* Summary of all agreements made under various divisions of original patent company.

Biotechnology Classification System

Biocodes	
100	**AGRICULTURE**
101	Agriculture (Not elsewhere classified (N.E.C.))
102	Bioherbicides/Pesticides
103	Diagnostics
104	Genetic Engineering
105	Growth Promoters
106	Herbicides/Pesticides/Disease Resistance
107	Improved Crops
108	Medicinal Plants/Drugs from Plants
109	Nitrogen-Fixation/Soil Enrichment/Inoculants
110	Propagation Techniques
111	Stress Resistance
200	**BIOTECHNOLOGY (N.E.C.)**
201	Animal Cell/Tissue Culture
202	Databanks/Programs
203	Energy/Biomass
204	Facility Construction/Large Equipment
205	Fermentation/Microorganism Development
206	Gene Machines
207	Household Products
208	Industrial Enzymes
209	Instrumentation (N.E.C.)
210	Marine Biotechnology
211	Mining Biotechnology
212	Reagents/Research Materials
213	Separation Equipment/Technology
214	Specialty Chemicals
215	Waste/Pollution Control

Biotechnology Classification System

Biocodes	
300	**FOOD/BREWING INDUSTRY**
301	Flavors/Fragrances/Coloring
302	Food Enzymes
303	Food Industry (N.E.C.)
304	Food Microbiology
305	Sweeteners
400	**HUMAN DIAGNOSTICS**
401	AIDS Tests
402	Allergy/Autoimmune Tests
403	Cancer Tests
404	Diagnostic Reagents
405	Diagnostics (N.E.C.)
406	DNA Probes
407	Drug Monitoring
408	Endogenous Substance Testing
409	Genetic Screening
410	Hepatitis Tests
411	Herpes Tests
412	Immunodiagnostics
413	In Vivo Imaging
414	Infectious Disease Test (N.E.C.)
500	**HUMAN THERAPEUTICS**
501	Anticancers (N.E.C.)
502	Biologicals
503	Blood Proteins
504	Cardiovascular Agents (N.E.C.)
505	Drug Delivery/Design/Formulation

Biotechnology Classification System

Biocodes

506	General Healthcare Products
507	Growth Hormones
508	Hormones (except Growth)
509	Interferons (IFN)
510	Lymphokines/Immunomodulators (except Interferons)
511	Therapeutic Antibodies
512	Therapeutic Enzymes/Enzymes Inhibitors (except tPA)
513	Therapeutic Proteins (N.E.C.)
514	Therapeutics
515	Tissue Plasminogen Activator (tPA)
516	Traditional Drugs
517	Transplantation
518	Vaccines
600	**VETERINARY**
601	Diagnostics (N.E.C.)
602	Feed Additives
603	Fertility/Hormones/Tests
604	Growth Promoters
605	Pesticides
606	Therapeutics
607	Vaccines
608	Veterinary (N.E.C.)

Source: **BioScan: The Biotechnology Corporation Directory Service**
The Oryx Press, Phoenix, 1987

Specific Research Areas by Biocodes for Bay Area Bioindustry Firms

Biocodes	Firm Name
101	Stauffer Chemical Sungene Technologies Corp.
102	Advanced Genetic Sciences Chevron Chemical Co. Zoecon Corporation.
103	Escagen Corp. Dohrmann/ Rosemount Analytical Div.
104	Advanced Genetic Sciences Escagen Corp. Zoecon Corporation
105	Chevron Chemical Co.
106	Genentech, Inc. Zoecon Corporation
107	Advanced Genetic Sciences Cetus Corporation Chiron Corporation Escagen Corp.. Zoecon Corporation Sungene Technologies Corp.
108	Genentech, Inc.
109	Advanced Genetic Sciences Cetus Corporation Chevron Chemical Co.
110	Escagen Corp. Zoecon Corporation
111	Advanced Genetic Sciences Zoecon Corporation
201	Bio-Response Condon Corp. Dnax Research Institute
203	Chevron Chemical Co. Genentech, Inc.
205	Chiron Corporation
206	Applied Biosystems, Inc. Bio-Rad Laboratories, Inc. Bioresearch
207	Genentech, Inc. Zoecon Corporation
208	Chiron Corporation Cooper Development Co. Condon Corp. Genencor, Inc.
209	3-M Diagnostics Applied Biosystems, Inc. Becton Dickinson Monoclonal Cetus Corporation Cooper Development Co. Dohrmann/Rosemount Analytical Genentech, Inc. Genencor, Inc. Syva Corp. Triton Biosciences, Inc. Varian

211	Chevron Chemical Co.
212	Applied Biosystems, Inc. Bio-Rad Laboratories, Inc. Biosearch Condon Corp.
213	Applied Biosystems, Inc. Bio-Rad Laboratories, Inc. Bio-Rad Laboratories, Inc.
214	Cetus Corporation Genencor, Inc. Henkel Research Group
215	Genencor, Inc.
301	Genencor, Inc.
302	Advanced Genetic Sciences Chiron Corporation Condon Corp. Genentech, Inc. Genencor, Inc.
303	Cetus Corporation
400	Becton Dickinson Monoclonal Bio-Response Hana Biologics, Inc.
401	Bio-Rad Laboratories, Inc. Cetus Corporation Chiron Corporation Cooper Development Co. Genentech, Inc.
402	3-M Diagnostics California Biotechnology Cooper Development Co. Syntex
403	Cetus Corporation Syntex Triton Biosciences, Inc.
404	Applied Biosystems, Inc. Bio-Rad Laboratories, Inc. Cooper Development Co. Triton Biosciences, Inc.
405	Syva Corp. Varian
406	Cetus Corporation Chiron Corporation Condon Corp. California Biotechnology
407	Micorgenics Corp. Syva Corp.
408	Bio-Rad Laboratories, Inc. Microgenics Corp. Monoclonal Antibodies Syntex
409	California Biotechnology
410	Chiron Corporation Cooper Development Co.
411	Syntex
412	Cetus Corporation Chiron Corporation Cooper Development Co. Genelabs, Inc. Microgenics Corp. Monoclonal Antibodies Peninsula Laboratories, Inc. Syva Corp. Syntex Xoma Corporation

413	Cetus Corporation Syntex Xoma Corporation
414	Cetus Corporation Chiron Corporation Xoma Corporation Microgenics Corp. Syva Corp. Syntex
500	Hana Biologics, Inc.
501	Applied Immune Systems, Inc. Cetus Corporation Cooper Development Co. Genentech Inc. Syntex Triton Biosciences, Inc. Xoma Corporation
502	Cooper Development Co. Genentech, Inc.
503	Bio-Release Chiron Corporation Cutter Laboratories Genentech, Inc.
504	California Biotechnology Dnax Research Institute
505	Alza Corp. California Biotechnology Collagen Corp. Cooper Development Co. Genentech, Inc. Liposome Technology, Inc.
506	Cooper Development Co. Collagen Corp.
507	California Biotechnology Genentech, Inc.
508	California Biotechnology Chiron Corporation Collagen Corp. Cooper Development Co. Condon Corp. Genentech, Inc. Microgenics Corp.
509	California Biotechnology Cetus Corporation Chiron Corporation Cooper Development Co. Genentech, Inc. Syntex Triton Biosciences, Inc.
510	Applied Immune Systems, Inc. California Biotechnology Cetus Corporation Chiron Corporation Cooper Development Co. Dnax Research Institute Genelabs, Inc. Genentech, Inc. Triton Biosciences, Inc.
511	Bio-Response Cetus Corporation Cooper Development Co. Xoma Corporation
512	California Biotechnology Chiron Corporation Condon Corporation Genentech, Inc.

513	California Biotechnology Chiron Corporation Cooper Development Co.
514	Applied Immune Systems, Inc.
515	Chiron Corporation Genentech, Inc.
516	Alza Corp. Cetus Corporation Genentech, Inc.
517	Cetus Corporation Xoma Corporation
518	Cetus Corporation Chiron Corporation Cooper Development Co. Genentech, Inc. Syntex
601	Monoclonal Antibodies
603	Monoclonal Antibodies
604	Chiron Corporation Genentech, Inc. Syntex
605	Zoecon Corporation
606	Alza Corp. California Biotechnology Cetus Corporation Genentech, Inc. Liposome Technology, Inc.
607	Cetus Corporation Chiron Corporation Condon Corp. Genentech, Inc. Syntex
608	California Biotechnology

Source: **Bioscan: The Biotechnology Corporate Directory Service,** The Oryx Press, Phoenix, 1987.

Chapter 5

Bioscience Research Programs and Resources At Major Bay Area Universities:

A Sample Survey

Chapter 5

Contents

Introduction	Page 5- 3
Survey Method	Page 5- 3
Summary of Responses to Interview Survey	Page 5- 4
Research Funding	Page 5- 4
Significance of Research	Page 5- 5
Research Facilities	Page 5- 6
Training	Page 5- 7
Prospects for Commercialization	Page 5- 8
Collaborations	Page 5- 9
Technology Transfer	Page 5- 9
Industrial Support	Page 5-10
Concerns and Constraints	Page 5-11
Recommendations from Researchers	Page 5-14
Conclusion	Page 5-15
Appendices	
A List of Persons Interviewed	Page 5-A-1
B Research Staff, Funding, and Areas of Interest	Page 5-B-1
C Major University Bioscience Departments and Research Programs	Page 5-C-1
D Survey Questions	Page 5-D-1

Introduction

Researchers at 4 universities were surveyed: UC Berkeley, UC Davis,UC San Francisco, and Stanford.

This survey study was undertaken to document the nature of the bioscience research programs and resources of the major Bay Area universities: University of California, Berkeley; University of California, Davis; University of California, San Francisco; and Stanford University. Researchers were asked about 1) programs and resources devoted to bioscience activities, 2) collaborations with researchers in other institutions and in bioscience industries, and 3) existing and future public education and awareness programs at these institutions.

Several researchers from each university were interviewed. Due to the importance of public education and awareness programs, campus public information/communication officials associated with bioscience research were also interviewed. The survey was not intended to be exhaustive.

Survey Method

Three ABAG Bioscience Task Force members who represent the University of California, Berkeley; University of California, San Francisco; and Stanford University, supplied names of bioscience researchers at their institutions. The author is grateful to Carol Copperud, Neils Reimers, Edward Blakely, and George Bruening for helping to arrange the interviews. Interviews lasted about an hour and were conducted in January, February, and July 1988. All researchers were asked to respond to a uniform set of questions, and most of them were asked to indicate areas of research using the biotechnology classification system (refer to page 4-G-1).

Summary of Responses to the Interview Survey

The following sections summarize the responses of university bioscience researchers and officials to the interview survey questions. Their comments, remarks, and observations are grouped and synthesized in the following categories, which appear in the same order as the questionnaire (Appendix D).

- *Research Funding*
- *Significance of Bioscience Research*
- *Research Facilities*
- *Training*
- *Prospects for Commercialization*
- *Collaborations*
- *Technology Transfer*
- *Industrial Support*
- *Concerns and Constraints*
- *Recommendations from Researchers to ABAG's Task Force*

Funding for bioscience research comes mostly from government sources.

Research Funding

- *Most Local Researchers Receive Substantial Funding for Bioscience Research*

Funding for faculty research does not seem to be a problem for the university researchers interviewed. Most researchers have healthy, long-term, and stable financial support for their bioscience research activities.

- *Funding is Supplied by Federal and State Agencies*

Almost all research funding is from federal and state government. Funding agencies most frequently named are the National Institutes of Health, National Science Foundation, American Cancer Society, and U. S. Department of Agriculture.

- *Students Need More Financial Support*

Financial support for students is more difficult to obtain. Funds for indirect costs, such as travel and books, come from gifts or from faculty patents and royalties.

- *More Solicitation of Non-governmental Research Funds Planned*

The importance of soliciting non-governmental financial support is well recognized. At the departmental or college level, full-time staff are designated to raise funds or initiate industrial support of biotechnology research. A few academic departments are planning to upgrade and expand their drive for more financial support.

Significance of Bioscience Research

The Bay Area is one of the major bioscience research centers in the world.

- *Early Bioscience Research was Conducted in Bay Area*

World class universities do fundamental biological research within the Bay Area. For example, researchers at UCSF and Stanford developed the original recombinant DNA technology, which has already led to mass-produced insulin, human growth hormone, etc., and formed the basis for the major growth of genetic engineering in the Bay Area.

- *Major Renovations and Improvements are Occurring in Bioscience Programs*

The significance of bioscience research in major Bay Area universities has increased tremendously in recent years due to strong commitment, emphasis, and priority in the following activities:

  - the construction/renovation of new research facilities is either almost complete, or in progress (due to review requirements), or in the planning stage;

- reorganization and expansion of existing teaching and research departments and programs reveals the broader scope and emphasizes the interdisciplinary nature of the new biology; and

- newer and larger multi-disciplinary research centers and programs are being promoted and established.

Bioindustry relies on university research for innovative breakthroughs.

- *Industry Reliance on University Research is Increasing*

The reliance of the biotech industry on university research is growing. Because only a few of the firms can afford to maintain the kind of research activity these universities perform, most of them look increasingly to universities for advances in research that lead to innovation, discovery, and application of biological products.

Research Facilities

- *Research Facilities Need to be Improved*

Many university researchers interviewed believe they have suboptimal facilities and research staffing. However, through cooperation with peers at universities and industrial firms, they function adequately.

- *Upgrading of University Research Facilities Expected*

Due to the construction of new laboratories, committed investment, and realignment and upgrading of equipment, campus research facilities will improve greatly in the near future. Some institutions are in the process of expansion and consolidation of their scattered facilities.

- *Students Do Not Have Enough Research Space*

Campus research spaces in some laboratories are very short due to California State Guidelines for Research Space. No bench space is allocated to post-doctoral researchers, techni-

cians, and undergraduate students according to those guidelines. Many researchers recommended the Guidelines be revised to accommodate a more reasonable space allocation.

Training

- *University Bioscience Programs in the Bay Area are Attracting Top Students*

Since the Bay Area is a recognized center of bioscience activities, great career opportunities in both private and public sectors can be encouraged. As a result, local universities easily attract quality students and post doctoral and other researchers from all over the world. Outstanding, active, and intensive training and education programs are offered in all research institutions visited.

- *Different Training Programs are Needed to Deliver Diverse Bioscience Skill*

Those interviewed were asked about the type of institution most suitable for the training of researchers and technical service personnel. The university researchers stated that most of their graduated students and trainees embark on research or teaching careers. Many believe state universities, community colleges, or extension services are more cost effective than universities for training lab technicians and other support staff.

Bioscience training programs are needed at community colleges and state universities to train technicians and production workers.

- *Special Training is Required for Even Service Workers Employed in Bioindustry*

Most researchers agree that the demand for well-trained bioscientific workers will create a shortage. They point out that specialized training is required for bioscience and biotechnology workers -- and is necessary for even janitorial service workers, since they will be working with sophisticated and expensive equipment and materials.

A shortage of trained bioscience and biotechnology workers is expected.

- *An Appropriately Trained Bioscience Labor Force is Crucial to Continued Bay Area Bioindustry Development*

Researchers point out that well tailored and broad-based bioscience training and educational programs in appropriate institutions will be crucial to continuing bioindustry development. As the industry becomes more capital intensive generally, a skilled labor pool becomes more important to sustain the industry's growth.

Prospects for Commercialization

- *University Research is Often Not Immediately Transferable to Commercial Product Development*

Since most university research programs are broad based and basic, almost all researchers consider that their efforts have very little immediate commercial value; they are not engaged in specific product research and development. Researchers quickly point out, however, that their work is fundamental to many bioscience applications, and they assert that research results will have very significant implications for industries. But most academic researchers feel the commercial aspect is of secondary importance.

- *University Bioscience Research has been Extensively Applied in Agriculture*

Many agricultural applications, both in plant and animal sciences, have been applied commercially and hold great prospects for the future. Farm animal embryo manipulations, characterization of single gene trait, molecular markers for gene manipulations, plant variety improvement, and post harvest plant researches are some examples.

Collaborations

- *Researchers at Universities and Companies Frequently Cooperate on Projects*

Extensive and intensive research collaborations between university and industry are cited. Many connections among researchers are established through students. Joint research and publication of results are common among faculty members at different institutions. Many research centers, either naturally or by design, develop broadly-based collaborations. Generally, they evolve from case to case.

- *Commercial Interests Should not Dictate University Research*

Academic collaborations with industry -- on a consultant or advisory basis -- are informal: mainly educational, by non-proprietary agreement, and with no specific contractual relationship. Informal and independent interactions are preferred to prevent university research from being dictated by industrial interests. Researchers believe that the proper role of university laboratories is to educate and train students, post-doctoral fellows, and associates without encumbrances from commercial activities and interests.

Bioscience has prospered in the Bay Area because of personal and professional cooperation and stimulation between researchers.

Technology Transfer

- *Mechanisms for Technology Transfer Between Universities and Industry Need to be Improved*

Special university development and technology and licensing offices are mostly in charge of technology transfer from laboratories to industries. Most researchers actively seek technology translations and other technology transfers, but many find the process works imperfectly and would encourage a more efficient technology transfer mechanism.

One institution invites other laboratories and research organizations -- both public and private -- to cooperate in a consortium

to ensure that new knowledge and technology are shared with others. Another institution is considering departmental efforts to facilitate the transfer more quickly and efficiently.

The University of California's Agricultural Extension Service has been identified as one of the effective networks for transferring newly-developed bioscience technology to farmers and producers. Extension experts and advisors can be trained in the new biology and in new techniques for dissemination of the technology.

- *Universities have Many Lucrative Bioscience Patents*

Many patents, reagents, and products are produced in university laboratories. In 1987, 30 percent of Stanford University's patents and about half of its royalties (about $3 million) were in bioscience. Similarly, UCSF had 93 patent issues and royalties of over a quarter million dollars from bioscience research in the same period of time. One researcher earned about a quarter million dollars from his royalties.

Industrial Support

Bay Area universities are benefitting from royalties on bioscience patents.

- *Industry's Financial Support to Universities is Ad Hoc Rather than Comprehensive*

Industry offers only ad hoc support or industrial affiliate programs to various university departments. Generally, these programs result from the initiative of the department or school and provide only short-term support, usually as a courtesy to the school, and typically, in all, about $15,000 yearly.

- *Important Industry Support for University Research is Non-Monetary*

Employees of companies involved with an industrial affiliate program derive benefits from attendance at university-sponsored meetings, access to research reports, and the privilege of laboratory visits. Many industries provide very beneficial non-monetary support to schools, such as free research materials (reagents, yeast, etc.) or free technical services and training.

- *Industry Financial Support of University Research will be Limited Until Company Profits Increase*

Industry does not seek specific technology or favor from cooperating academia, since most bioscience companies are rich in technology -- one of the main reasons for their existence. In addition, most biotechnology companies are not yet profitable and therefore unable to give large sums of money.

Industry support for university research will increase as bioscience companies become more profitable. Industry support is often non-monetary.

Concerns and Constraints

- *Public Education is Important to University Bioscience Researchers*

All universities and most researchers are engaged, to some degree, in educating the public about the biosciences. There are plans to expand the scope and intensity of these programs. For example:

- Principal investigators address national, state, and local legislators and elected officers (Santa Clara County, San Francisco Board of Supervisors, Alameda County Council of Mayors, etc.).
- Organized tours of university research laboratories of officers and public are conducted by invitation.
- Partnership programs between high school science teachers and university biological science researchers usually include lectures and provision of free lab materials and used equipment.
- Bioscience educators participate in the design of statewide life science secondary education curricula.
- Academic researchers sponsor bioscience workshops for science editors of all media.

- *Decision-makers and the Media Need to be More Informed About Bioscience*

By and large, most researchers and university officers think media reporters and politicians and their staffs are not sufficiently knowledgeable about the new bioscience. Those inter-

viewed recommend that ABAG be used as a forum to convey the understanding that there are very technical and important issues which require governmental action and that ABAG provide a mechanism to educate the decision-makers. ABAG members could function as technically informed leaders who have easy access to expert advice. Researchers and university officers fear that due to misplaced emotions, feelings, and sympathy, tens of thousand of lives will be cut short which might have been extended with new biotech remedies.

Informing the public about the nature of bioscience -- both its risks and prospects -- is important to university researchers.

- *Public Distrust of Bioscience Concerns University Researchers*

University officers and researchers are very much aware of and gravely concerned about the expressions of distrust from neighbors and concerned groups on university bioscience research activities. Those interviewed believe that a lot of resources are expended on what they consider to be unwarranted public concerns, resulting in costly delays to research activities. One university estimated the postponement of construction cost at about two million dollars and two years of research time. These public concerns also increase research costs because additional security costs are incurred and research animals may need to be procured from more costly sources.

- *New Bioscience Research Facilities at All Four Bay Area Universities have been Delayed by Public Opposition*

All four universities surveyed are experiencing delays in new bioscience research laboratory construction due to public opposition. Although the nature of the dispute at each campus is unique, the underlying reasons for the opposition, as cited by academic researchers, include 1) ignorance and fear of science itself, 2) fear and suspicion of the institution where the program is to be carried out, 3) fear of change and fear of technological accidents together with concern about the safety of genetic engineering, and 4) various political interests among the opponents.

- *University Public Relations Offices are Becoming More Sensitive to Public Concerns About Bioscience*

The success these universities have had in dealing adequately with public opposition to their bioscience projects seems to depend on the number of times they have experienced their opponents' arguments. While at first the schools' public or community relations offices seem unprepared for the issues and the intensity of bioscience opposition in public meetings, they eventually come to understand, if not agree with, the other points of view and organize effective replies.

Blocking construction of new bioscience laboratories could result in costly delays and disruption of timely research.

- *University Bioscience Researchers Feel Some of Their Colleagues are Partially Responsible for Public Concerns*

More than half of the researchers and campus officials surveyed believe that some researchers themselves are responsible for the public concern because:

- their use of difficult technical language has destroyed effective communications with the public and media;
- they have been guilty by omission, when specific statements about planned uses of new facilities could have prevented many neighbors' concerns and suspicions; and
- they have insensitively provoked the community by committing numerous violations of safety regulations.

- *University Safety Procedures are Often More Stringent than Required by Law*

University researchers and officials claim that campus environmental safety systems, procedures, and facilities are in place to respond to any potential hazard to humans or animals from biological, chemical, radioactive materials. Most new researchers are required to pass safety, training, and certification tests, which are far more stringent than those required by the law.

- *Correct Research Procedures are Rarely Violated Deliberately*

Although outright and deliberate defiance of regulations is a rare occurrence, sometimes established safety rules and regulations are not strictly followed. For example, numerous cita-

tions were issued recently by inspecting authorities. The institution then had to overcome aroused neighborhood mistrust and public complaints. As a result, research was affected and in this way researchers became more aware of the political repercussions which can arise from public concerns. Also, university officials have developed better communications with bioscience researchers who are used to functioning independently.

Recommendations from Researchers to ABAG's Bioscience Task Force

Many university researchers state they are adhering to safety procedures more stringent than required by law.

- Some researchers believe that now is a good time to campaign for bioscience industries in the Bay Area. Potentially, ABAG could encourage joint and concerted efforts in public eduction, and ensuring general region-wide policies, standards, and regulations.

- Since bioscience industry is relatively new and fluid, researchers recommend that ABAG member governments take into consideration the industry's inherent changing and evolving characteristics when designing policies and regulations. For instance, responsive rules and regulations should be in place to deal with the transport, application, and storage of genetic materials, pesticides, and such substances.

- Researchers recommend that ABAG work to offer a stable political and social environment for the bioscience industry, to allow it to grow into one of the leading industries in the Bay Area. They maintain that the industry needs realistic long term support from local governments in order to attract both domestic and foreign investments. According to them, a positive public image is very important to attract capital and other growth in the bioscience industry. If the Bay Area fails to support the industry's growth, it will have to grow and develop where conditions are more hospitable.

- Almost all bioscience researchers interviewed are more than willing to serve as a resource to ABAG's member governments. Many of them consider their efforts to serve

communities, governments, and industry as part of their mission and responsibilities.

- Researchers recommend that ABAG sponsor regular meetings between university researchers and public officials and their staffs for the purpose of discussing important bioscience development issues as they arise and evolve. Researchers prefer to communicate with them before an issue reaches crisis proportions in any community.

A forum is needed for communication between the bioscience community and local decision-makers.

Conclusion

That universities offer essential resources to the developing bioscience industry, just as they contributed to the growth of high-technology and the computer industry, is well recognized in the Bay Area. Large amounts of federal and state bioscience research funds are granted to Bay Area university researchers, many of whom are nationally and internationally well-known university faculty members. Many of their research results are transferable to practical applications, and many industrial "spin-offs" have occurred, creating employment opportunities and a host of other benefits. The researchers interviewed are very hopeful for the future growth of the bioscience industry in the San Francisco Bay Area.

Universities are also available to support Bay Area governments at all levels in making rational decisions with regard to promotion and regulation of bioscience industries in their jurisdictions. University researchers are willing to advise and recommend a rational course of action on a wide range of very technical and significantly important bioscientific issues facing governments. Since the bioscience industry is relatively new and complex, and since it does not have all the answers to potential side effects and the ethical issues that could be involved, governmental decision makers could benefit from using university experts in the design and implementation of policies and programs to support the industry's growth.

University researchers are an important resource to local governments.

As a valuable resource, university bioscience activities in the region need to be preserved, protected, and developed with great care. The uniqueness of these research and teaching

institutions has been challenged in recent times. Bay Area superiority in the biosciences could be lost if essential political support is not provided. Already a few potential researchers have shunned the Bay Area and a few others are contemplating leaving Bay Area institutions for fear of possible hindrance to their research activities.

The Bay Area's superiority in the biosciences is at risk if university research is not encouraged.

University bioscience research is controversial and scientists have confronted sensitive issues. Four leading San Francisco Bay Area universities are facing opposition to construction of new bioscience-related research facilities by neighborhood groups, animal rights activists, and environmentalists.

The areas of opposition to facility expansion are diverse. There are the traditional urban development issues -- neighbors' resentment of university encroachment into residential areas creating housing, traffic, and parking problems. In addition, some people are concerned about animal welfare in research laboratories as well as the potential side effects which could result from accidental release of hazardous substances. In a sense, this is a classic locational conflict problem -- establishing or expanding potentially hazardous research facilities in the midst of a highly populated urban area.

Another dimension of the conflict is the incidence of the cost and the distribution of the benefits of the bioscience research. Clearly, the benefits and costs do not observe political boundaries: regional, national, or even international benefits will result. On the other hand, most of the cost (at the least, the costs of uncertainty) will be born locally. Still another dimension of these complex issues is the time horizon of the benefits and costs. Since many effects may be unknown for some time, the long-term effects are difficult to assess.

Campus officials are conscientiously trying to be good neighbors in their communities with unexpectedly negative results. The discrepancy between intent and public perception has caused, in part, public concern for these institutions. Better campus-wide coordination in dealing with the public and local governments is being called for.

For the purpose of public education, universities need to identify bioscientists who communicate well and articulate complicated new concepts and issues in simpler terms. Many univer-

sity-sponsored public educational programs for the media, public officials, and high school science teachers should be augmented and extended. As university bioscience researchers experience the political repercussions from public concerns about their research, their accessibility for campus community relations officials has greatly improved. Better coordination between researchers and campus officials in dealing with public concerns may require the upgrading of university community and public relations offices. There needs to be more cooperation between university officials of different campuses in exchanging their experiences with expressions of public concern about bioscience research. Perhaps ABAG needs to consider sponsoring regularly scheduled meetings between university researchers and public officials and their staffs to discuss these important bioscience issues and concerns.

University researchers welcome the opportunity to participate in public education on bioscience.

Finally, ABAG could serve as a facilitator and clearinghouse for regional bioscience industrial development programs, policies, and regulations. Through these efforts, bioscience industrial development could become an important segment to a regional economic development plan.

List of Persons Interviewed

University of California, Berkeley

Wilford R. Gardner
Dean, College of Natural Resources

Robert Glaeser
Professor, Department of Biophysics

Raymond Colvig
Manager of Public Information, Public Affairs Office

University of California, Davis

Gary Anderson
Professor, Department of Animal Science

Richard Michelmore
Professor, Department of Vegetable Crops

Donald Nevins
Professor and Chairman, Department of Vegetable Crops

Tilahun Yilma
Professor, Veterinary Medicine, Microbiology, and Immunology

University of California, San Francisco

David Ramsay
Senior Vice Chancellor, Academic Affairs

Bruce Alberts
Professor and Chairman, Department of Biochemistry and Biophysics

Alexander Margulis
Professor and Chairman, Department of Radiology

Henry Ralston
Professor, Department of Anatomy and Chair of the Academic Senate

William J. Rutter
Professor of Biochemistry and Director, Hormone Research Institute

Michela Reichman
Assistant Chancellor - Communications

Thomas G. Gwin
Assistant Chancellor - Public Service Programs

Barbara Atkins
Director - Community and Government Relations

Stanford University

Paul Berg
Professor, Department of Biological Sciences
Director, Center of Molecular Genetic Medicine

Stanley N. Cohen
Professor, Department of Genetics

Stan Falkow
Professor and Chairman, Medical Microbiology Department

Stanford University (continued)

Philip C. Hanawalt
Professor and Chairman, Department of Biological Sciences

Larry Horton
Associate Vice President for Public Affairs

Andy Doty
Director of Community Relations

U.S. Department of Agriculture
Agricultural Research Service
Albany, California

Gerald G. Still
Director, Plant Gene Expression Center

Lawrence Berkeley Laboratory

Paul H. Silverman
Associate Laboratory Director for Life Sciences
Director, Donner Laboratory

Research Staff, Funding, Areas of Interest

Staff Size

Researcher	Principal Investigator	Post - Doctors	Graduate Student	Undergraduate Student
Berg	12	50-60	30	4-5
Cohen	1	12	5	3
Falkow	1	14	4	13-15
Hanawalt	32	60	90	300
Gardner	150	----	500	800
Glaeser	1	3	3	3
Silverman	150	----	100	700
Anderson	1	3	9	3
Michelmore	1	3	8	0
Nevins	14	20	47	80
Yilma	1	3	6	0
Alberts	50	95	67	0
Margulis	10	10-12	3	0
Ralston	25	40	20	0
Rutter	3	25	2-3	0
Still	14	19	4	28

Funding

Researcher	Amount	Duration	Years in Research	Sources
Berg	----	5 years renewable	35	NIH, ACS, NSF, USDA, Foundations, Industries
Cohen	700k/yr	2-10	20	NIH, ACS
Falkow	500k/yr	5-10	28	NIH, DOE, U.S. Army
Hanawalt	5MM/yr	7	25	NIH, NSF, DOE, ACS, Institute on Aging
Gardner	16MM/yr		100	2/3 State of California 1/3 Federal Agencies
Glaeser	400K/yr	3-15	22	NIH
Silverman	35MM/yr	1- 3	50	NIH, DOE, NASA, EPRI
Anderson	250K/yr	2- 3	14	USDA, Industries
Michelmore	400K/yr	1- 3	12	USDA, DOE, Industries
Nevins	3.4MM/yr	1- 3	40	NSF, USDA, NIH, DOE
Yilma	1.5MM/yr	5	24	AID, USDA, NIH
Alberts	9MM/yr	1- 5	22	NIH, NCI, NSF, NIGMS
Margulis	15MM/yr		32	NIH, DOE, Industries, Foundations
Ralston	7MM/yr	3-5-7	30	NIH, NSF, State, Private
Rutter	1.5MM/yr	5-7	19	NIH, NSF
Still	3MM/yr		20	USDA, NIH, DOE

Institutions

NIH	National Institutes of Health
DOE	Department of Energy
ACS	American Cancer Society
NSF	National Science Foundation
USDA	United States Dept. of Agriculture
NCI	National Cancer Institute
AID	Agency for International Development
NASA	National Aeronautic and Space Administration
EPRI	Electric Power Research Institute
NIGMS	National Inst.of General Medical Sciences

Areas of Research Interest	
Berg	• macro molecular structure • genetic chemistry and engineering • protein chemistry
Cohen	• genetics
Falkow	• infectious diseases • genetics: molecular and cell biology
Hanawalt	• theoretical biology • animal and plant molecular structure • ecology
Gardner	• agricultural related biology
Glaeser	• cell membrane protein • protein crystallography • molecular biophysics
Silverman	• mapping and sequencing the human genome • cell and molecular biology and chemical biodynamics
Anderson	• animal development processes utilizing the techniques of micromanipulation of animal embryos
Michelmore	• classical and molecular research on plant disease resistance
Nevins	• new germ plasma • major crop quality improvement and transportation
Yilma	• virology • molecular biology
Alberts	• biochemistry and biophysics for medical applications
Margulis	• magnetic resonance imaging • imaging techniques for diagnosis and treatment of diseases
Ralston	• use of genetic materials for pain research • imaging research
Rutter	• isolation and characterization of hormone and growth factors • protein engineering • regulations of gene expressions
Still	• biology of major crop plant gene expression

Major University Bioscience Departments and Research Programs

University of California, Berkeley

Cancer Research Laboratory
Department of Biochemistry
Department of Genetics
Department of Molecular Biology
Virus Laboratory

University of California, Davis

Department of Biochemistry and Biophysics
Department of Genetics
Department of Pomology
Department of Viticulture and Enology
Department of Plant Pathology
Department of Animal Science
Department of Vegetable Crops
School of Veterinary Medicine
School of Medicine

University of California, San Francisco

Brain Tumor Research Center
Cancer Research Institute
Hormone Research Laboratory
Laboratory of Radiobiology and Environmental Health
Mass Spectrometry Facility
Metabolic Research Unit
Ocular Oncology Research Unit

Stanford University

Cancer Biology Research Laboratory
Department of Biochemistry
Department of Biological Chemistry
Department of Genetics
Department of Medical Microbiology
Department of Pathology
General Clinical Research Center

Lawrence Berkeley Laboratory

Biology and Medicine Division
Donner Laboratory
Laboratory of Chemical Biodynamics
Laboratory of Chemical Dynamics

Survey Questions

(I) Describe bioscience research you are engaged in.

Staff size

- principal investigators
- researchers, post-doctors
  graduate students, undergraduate students

Funding

- amount
- sources
- duration
- how long have you been engaged and how much longer will it continue?
- past research

Interest

- bioscience areas of the most interest to you

Prospects

- technologies showing the most promise for commercialization
- financial and staff committed to them

Facilities

- laboratory facilities and staff adequacy for the research
  if insufficient, what other arrangements are being or can be made?

Training

- undergraduate and graduate training and education programs for careers in the bioscience field

(II) Collaborations (university-industry research interactions)

- existing relationships with Bay Area and other area bioscience firms
- firms who have interactions or ties with Universities
- nature of those ties
- their histories
- type of agreements, formal or informal
- use of staff exchanges
- interactions with other university researchers
- existing programs and measures to promote industrial support of researchers

List of programs in:

- direct funding of research through contracts and grant funding
- gifts and endowments for research and education
- university-industry exchange programs and student internships
- co-sponsorship of specialized programs

(III) Concerns and constraints

What news media provide information to the public regarding bioscience-related activities on campus? Are there any outreach programs and means of communication in a positive way?

Are there any constraints or concerns on bioscience activity from local governments and the public ?

Have researchers been partly responsible for some of the public concern about bioscience research? If so, how?

What can be done by local governments and/or universities to better inform the public of the nature of bioscience research and its benefits to the community?

(IV) Any recommendations on what ABAG's Task Force should pursue?

Chapter 6

Biotechnology Regulations:

State and Federal Regulatory Framework and Local Options

Chapter 6

Contents

Introduction	Page 6- 3
Federal Regulatory Framework	Page 6- 4
State Regulatory Framework	Page 6- 6
Conclusions on State and Federal Regulatory Systems	Page 6- 9
Local Regulatory Framework	Page 6-11
Conclusions Regarding Local Government Involvement	Page 6-14
Local Government Needs	Page 6-15
Strategic Alternatives	Page 6-16
List of Persons Interviewed	Page 6-20
Bibliography	Page 6-21

Introduction

According to the handbook, **Biotechnology: California Permits and Regulations**, "Biotechnology, simply defined, is the application of biological systems and organisms to technical and industrial processes." Common examples of industries that use biotechnology processes include wine and beer fermentation, baking, and animal husbandry. Since the early 1970's, however, our added ability to manipulate the genetic material of living organisms has given these industries new tools: recombinant DNA (rDNA), cell fusion, and novel bioprocessing techniques. These new techniques are referred to as "new biotechnology."

Public concern over the unknown nature of biotechnology risks is affecting federal, state, and sometimes local approval procedures.

Whether or not the products of biotechnology are inherently different than existing products can have important implications for how research and the use of products are regulated. If the products of biotechnology are not inherently different, then existing regulatory mechanisms combined with public leadership, education, and communication should be reasonably adequate at minimizing risks and providing the desired level of protection of public health and safety and the environment. If these products are inherently different, then it is possible that new risks, which are not as yet detected and analyzed in the current regulatory network, will be created. In addition, whether or not these risks are real may be irrelevant: if the public is anxious about the unknown nature of biotechnology risks, then this fact alone could justify proceeding with caution.

As federal and California agencies position themselves to regulate the new range of research and products, local governments will often find themselves closest to public concerns about biotechnology. County and city governments in California have several options for responding to and preparing for increases in biotechnology research and product development applications. The state and federal regulatory environment and lessons learned from local government involvement to date must be considered in developing these options.

Federal Regulatory Framework

Important Elements

- *Dispersed, but Comprehensive Authority*

Officials state that the federal regulatory framework as modified is so substantial that no new product should "slip through the cracks." For example, if no specific regulations apply, EPA has broad discretion through the Toxic Substances Control Act to regulate bioengineered microbes as "new chemicals."

Federal agency regulation of bioscience occurs principally through the FDA, USDA, OSHA, and EPA.

- *Overlapping Agency Jurisdictions*

Although Federal agencies have resolved most coordination problems through the Biotechnology Science Coordinating Committee, some problems related to overlapping authority remain.

- *Applications Reviewed Using a Case-by-Case Method*

All agencies conduct reviews on a case-by-case basis. The advantage of this approach is that new scientific questions can be asked and new data introduced as products are developed. This in-depth approach on specific issues recognizes the evolutionary nature of biotechnology. Unfortunately a case-by-case method increases uncertainty for industry and creates a decision-making process which is more difficult for local officials and the public to trace.

- *Product Testing Out-of-Doors Is Challenging Regulatory Process*

Perhaps the most challenging products to regulate under existing statutes are those which are intended to survive in the open environment (e.g. pesticides, fertilizers).

Background

Although Congress has considered new, centralized regulation of biotechnology on several occasions, no statutes specific to biotechnology have been passed. The federal government has determined that most biotechnology activities can be regulated through existing statutes.

In 1984, in order to clarify agency jurisdictions and eliminate redundancy, the President established the Biotechnology Science Coordinating Committee within the Office of Science and Technology Policy. The agencies which participated in this committee included the Environmental Protection Agency, the United States Department of Agriculture, the Food and Drug Administration, the Occupational Safety and Health Administration, and the National Science Foundation.

This committee published a policy document in the Federal Register in June 1986 entitled "The Coordinated Framework for Regulation of Biotechnology," that was intended to clarify which agencies would have regulatory responsibilities for specified biotechnology activities. The Coordinated Framework addresses the regulatory policies of EPA, FDA, OSHA, and USDA; it addresses the research policies of NIH, EPA, OSHA, and USDA. Some new regulations have been proposed to clarify and cover identified inadequacies.

Most federal regulation of bioscience uses existing statutes; no laws governing biotechnology have been passed.

State Regulatory Framework

Important Elements

- *Applications Reviewed Case-by-Case*

State agencies process permit applications on a case-by-case basis. In some cases, a State agency will review carefully the Federal permit decision. For example, both bioengineered pesticide applications and pharmaceutical manufacturing facilities are reviewed carefully by the State.

- *Agencies Have Designated Contact Persons*

State agencies have designated contact people within their regular technical staffs who are responsible for biotechnology related activities. Both the Department of Health Services and the Department of Food and Agriculture have requested new funds to hire people with biotechnology related expertise.

- *CEQA Must Be Considered*

Each State agency that issues permits affecting the environment must satisfy the California Environmental Quality Act. The Task Force has taken steps to clarify each state agency's procedures. That work is not yet complete.

When issuing permits which could affect the environment, state agencies comply with the California Environmental Quality Act.

Background

- *Interagency Task Force Created*

Biotechnology regulation on the State level has paralleled that of the federal government. No new legislation specific to regulation of biotechnology has been passed. An executive order creating the Interagency Task Force on Biotechnology was signed by Governor Deukmejian in 1985. This executive order establishes the California Department of Commerce as the lead agency and the California Department of Food and Agriculture (CDFA), California Department of Health Services (DHS), the California Department of Fish and Game, the Environmental

Affairs Agency, the Department of Industrial Relations, and the Water Resources Control Board as member agencies. The Air Resources Board, the Department of Conservation, the Department of Forestry, the Office of Planning and Research, and the Office of Administrative Law are also represented. The Interagency Task Force was given specific authority to accomplish several different tasks which included evaluating the adequacy of federal and state regulations, coordinating regulatory agencies, and educating industry and the public.

The Interagency Task Force first set out to clarify regulatory jurisdictions, and has prepared, **Biotechnology: California Permits and Regulations**, which contains detailed information on federal and state permitting authority for numerous categories of bioscience products.

In 1985, Governor Deukmejian created an Interagency Task Force on Biotechnology.

- *Interagency Task Force Goals and Objectives*

The two-pronged goal of the State was first articulated in ACR 170: "...to promote the biotechnology industry while at the same time protecting public health and safety and the environment." Although this language is not repeated explicitly in the executive order, all members of the Task Force understand this goal to be operative. The order specifies that:

1. The Task Force shall serve as a resource and repository for expertise and information on biotechnology that could be utilized by appropriate state agencies.

2. The Task Force is charged with the following nonexclusive responsibilities:
   a. to evaluate and determine the adequacy of federal and state regulations affecting the biotechnology industry;
   b. to coordinate and assist in the formulation of state policies affecting the biotechnology industry;
   c. to serve as the principal liaison between the State of California and federal agencies, including the President's Cabinet Council on Biotechnology, on matters affecting the biotechnology industry;
   d. to develop educational programs in biotechnology for the benefit of the general public, to the extent that the Task Force determines that such programs are necessary; and

e. to provide information to new California biotechnology firms on compliance with California statutory and regulatory requirements.

- *Legislators Introduce Bills*

Members of the Legislature have introduced several bills which would either promote or regulate biotechnology. In 1982, Assemblyman Torres introduced AB 3549. This bill would have required all research conducted by the State or receiving State funds to comply with National Institutes of Health guidelines. The bill was passed by the Legislature but vetoed by then Governor Brown.

In August 1984, Assemblyman Sam Farr, Chair of the Committee on Economic Development and New Technologies, introduced Assembly Concurrent Resolution (ACR) 170. This resolution passed in less than a month. ACR 170 required the Assembly Office of Research to "review all existing, pending, and elapsed state and federal regulations affecting California biotechnology so that the State could make informed decisions about how to promote biotechnology while protecting health and safety and the environment."

- *Legislative Subcommittee on Biotechnology Created*

In February 1985, Assemblyman Farr created a standing Subcommittee on Biotechnology within the Committee on Economic Development and New Technologies. In April 1985, the Assembly Office of Research submitted the completed ACR 170 study to the Assembly. It contained several recommendations, including the creation of a Task Force similar to the federal Biotechnology Science Coordinating Committee.

The California Assembly's Committee on Economic Development and New Technologies is concerned with both regulating and promoting biotechnology.

Simultaneously with the Legislature's actions, several state agencies were becoming more aware of the new economic promise and potential regulatory problems of biotechnology. In 1983, the State Department of Commerce issued a report entitled, "Job Creation for the Eighties." Biotechnology industries were identified as some of the most likely growth industries.

- *Applications for Field Testing Submitted*

In 1984, the first biotechnology permit application for a planned field experiment using a genetically engineered microbe was submitted to the California Department of Food and Agriculture (CDFA).

- *Two Laws Affecting Biotechnology Approved in 1987*

In 1987, two bills affecting biotechnology were signed into law. The first, AB 5 (Duplissea), established a 10-member Blue Ribbon Biotechnology Curriculum Advisory Committee to advise the Superintendent of Public Instruction on whether to include in the state's biology curriculum units to increase pupil understanding of molecular biology and the biotechnology industry. A second law, AB 1459 (Farr), established a biotechnology clearinghouse within the State Department of Commerce to act as a referral service for information on biotechnology research, regulations, product development, and policy issues.

The State created a biotechnology clearinghouse to act as a referral service for industry, researchers, and the public.

Conclusions on State and Federal Regulatory Systems

- *Existing Laws Seem Adequate*

Both the federal Biotechnology Science Coordinating Committee and the state's Interagency Task Force on Biotechnology have concluded that existing laws and regulatory authority seem adequate to regulate the wide range of biotechnology products and processes. Every product is controlled by at least one set of regulations. All new bioengineered microbes not already regulated by another agency will be handled under EPA's Toxic Substances Control Act (TOSCA) as a "new chemical."

- *Jurisdictional Overlap Provides Additional Safeguards*

Some definitional discrepancies and areas of ambiguity remain. For example, there is some question whether all products intended for environmental release should be reviewed under a FIFRA (pesticide) procedure rather than the TOSCA (new chemicals) procedure. The courts have concluded that both

laws require an implicit weighing of risks and benefits. TOSCA places the burden of proof on EPA, however, whereas FIFRA places the burden of proof on the applicant.

All state and federal agencies conduct permit application reviews on a case-by-case basis. This flexibility is desirable because of the particular scientific questions which must be asked depending on the particular product. On the other hand, this case-by-case review creates a less certain environment for industry and a decision-making process which is more difficult for local officials and the public to trace.

Both the federal government and the state have concluded that existing laws adequately regulate all biotechnology products.

- *Guidelines and Permitting Procedures Under Development Need to be Finalized*

Standard operating procedures, such as risk assessment guidelines, will be developed over the next several years. For example, EPA has issued a strategy for developing risk assessment guidelines for bioengineered microbes intended for environmental release. In the long run, this procedure should provide a more certain regulatory environment which would greatly benefit applicants, local government, and the public.

- *State Regulation Should Complement, Not Duplicate Federal Regulation*

State regulations generally complement federal agency reviews. Several state laws duplicate the federal regulatory review process. Thus, the scientific review and data evaluation are also duplicated. Both the Legislature and the Task Force have concluded that new state regulations should not be created if the federal regulations are adequate. Several state officials, when questioned about the role of local government, stated that local government should not duplicate existing federal and state reviews.

- *Having State Agency Contact Persons Helps Local Officials*

State agencies have designated existing personnel as biotechnology contacts within their agencies, and they are also beginning to staff themselves with specific bioscience and risk communication expertise. Both CDFA and DHS have submitted budget change proposals to hire additional people for this purpose.

- *More Communication Needed Between Federal, State, and Local Officials*

State officials believe that local officials should be informed, but that special ordinances and permit procedures are redundant in those cases where federal and/or state regulations already exist. State officials believe that the lines of communication with local governments could and should be improved. The Interagency Task Force has not reviewed local government regulations.

Until better understood, the network of State and Federal regulatory agencies is likely to be perceived as confusing and unpredictable by local government officials and the public. Recognizing that local officials needed a single point of contact, both the California Department of Commerce and the federal Interagency Task Force have established information centers which local governments can use.

Only when federal review procedures are found to be inadequate should California adopt further biotechnology regulations.

Local Regulatory Framework

Background

Ideally, local governments would have strategies allowing them to respond quickly and efficiently to all types of biotechnology proposals, whether for pesticide experiments or for manufacture of oil consuming microbes.

Unfortunately, it is difficult to know exactly what types of applications are likely to be submitted in the future. To date, local governments have been involved in three categories of regulatory activity related to biotechnology 1) regulating operations of existing research facilities, 2) granting permits for new research facilities, and 3) reviewing experimental field test permits for agricultural products.

- *Regulating Existing and Proposed Facilities*

Several Bay Area cities have passed ordinances requiring all research facilities to conform with research guidelines issued by the National Institutes of Health. The NIH already requires

that research operations receiving funds from NIH comply with these guidelines. Most private (non-NIH) funded firms say that they voluntarily comply with these guidelines. Therefore, although this type of local regulation is not thought to be burdensome, it may deter industry from locating at a particular site, in that it signals political or citizen opposition.

Local governments may review the scope of proposed bioscience activities when considering development applications.

Local governments have permit authority over certain new uses and buildings. Discretionary permit authority allows cities and counties to invoke the environmental review process under the California Environmental Quality Act. Two proposed biotechnology research facilities have caused considerable controversy during the past year leading to preparation of Environmental Impact Reports (EIRs) -- UC San Francisco's Laurel Heights campus and Stanford's proposed biological research facility. The UCSF project has caused neighborhood concerns related to traffic impacts and the adequacy of parking, toxic chemicals, radioactive substances, and animal research. Final resolution of the proposed project is pending. Santa Clara County recently prepared an EIR for the Stanford project. Potential impacts and public concerns included the treatment of animals in lab testing, amount of toxics used, and methods of handling the disposal of toxics. Juanell Waldo, Planner for Santa Clara County, indicates that the EIR was a valuable educational tool. Consultant costs and work delays caused by the EIR are estimated at $750,000.

- *Regulating Experimental Field Tests: Monterey's Experience*

California has been home to the first two approved outdoor field tests of bioengineered products in the country. Although deliberate release projects represent a very small fraction of biotechnology work, such tests have received considerable publicity.

Both tests involved modified ice nucleating bacteria. One of the tests, Advanced Genetic Sciences' product "Frostban," was originally proposed to be tested in Monterey County on strawberry plants. Because the formal permit application process involved only EPA, CDFA, and CDHS, the firm did not notify or educate county officials.

Once the application became public, however, substantial pressure was placed on local officials to stop the experiment. In response, the Board of Supervisors adopted a local ordinance requiring a use permit for bioengineered organism testing. This ordinance gave Monterey County permit authority and therefore authority to require AGS to conduct an EIR. AGS withdrew its application without an EIR ever having been prepared. (It is unclear to what extent the cost of preparing the EIR was a factor in the withdrawal and also whether the public opposition played a part in it.) Monterey County's ordinance is subject to challenge on the basis that the State's statutes on pesticide use preempt local control.

Several local jurisdictions have adopted ordinances specifically on bioscience.

AGS subsequently hired a public relations specialist who approached officials in both San Benito County and Contra Costa County regarding the experiment. AGS held meetings with the two communities and with local public officials. According to Nancy Andrews of EPA, both Hollister (San Benito County) and Brentwood (Contra Costa County) officials were enthusiastic about AGS conducting experiments in their areas. Brentwood was eventually selected for technical reasons.

Following selection, there was a fair amount of public concern and opposition about the tests from both local residents and people who lived outside the County. Vandals tried to stop or call attention to the test by destroying some of the strawberry plants. AGS has recently begun a second round of testing. Public opposition seems to have quieted slightly.

The second instance of experimental field testing involves the "ice-minus" bacterium developed by a UC Berkeley scientist. These experiments were proposed for Tule Lake in Siskiyou County in northern California. The group, Californians for Responsible Toxics Management, filed a lawsuit against the University to halt the tests. The University agreed to write an EIR even though it was convinced that one was not needed on technical grounds. The preliminary EIR review found no significant adverse environmental impacts.

Conclusions Regarding Local Government Involvement

The following conclusions are drawn from recent local government experiences with applications involving bioscience:

- *Public Looks to Local Government to Protect Them on Biotechnology Issues*

Local governments are expected to be responsive to public concerns regarding biotechnology, even though they may not be the agencies most appropriate for implementing biotechnology regulation.

- *Bioscience Firms are Concerned About How Local Government Actions Affect Them*

Local governments are expected to respond to public concern about bioscience activities even though they are not implementing agencies under state and federal law.

Actions of local governments affect both the costs incurred by the applicant/research firm and, in some cases, the ultimate decision to locate a facility or proceed with a field test.

- *Most Local Governments are Unprepared to "Regulate" Bioindustry*

Local governments have not invested a lot of resources in predicting how they will be involved in reviewing future permit applications or how they will respond to any public concerns.

Local governments do not have biotechnology experts on their staffs who understand either the technical and scientific aspects of permit applications or the larger system of federal and state regulations governing biotechnology. County Health Officers and County Agricultural Commissioners and their staffs can, to some extent, build on their related existing expertise when a biotechnology-related application comes before them. Planning staffs have no significant knowledge in related fields.

- *Local Officials May Not Know Whom to Contact in State and Federal Agencies*

Local officials and staff who need to respond to public concerns regarding proposed biotechnology projects do not necessarily know which state and federal regulators could supply them with

useful information. In certain situations, lines of communication are quite good. For example, when an experimental pesticide permit comes before the State Pesticide Regulatory Evaluation Committee, the CDFA now automatically notifies the County Agricultural Commissioner. Other state agencies also notify their local counterparts.

- *Local Governments Will Receive More Applications Involving Bioindustry*

Applications for experimental field tests and for major new research buildings/industrial parks will continue to be controversial, with interaction between university/medical research facility expansion and the local community increasing in the future.

As local governments receive more applications involving bioscience, they will need to be more informed about possible risks and opportunities.

Local Government Needs

Based on the above history, the following local government needs can be identified:

- *State and Federal Procedures for Receiving Public Input*

The public wants to have a role in the decision-making process. Local governments need the State to be more active in recognizing the legitimate role of local public opinion in permit decisions. When processing applications, both actual and perceived risk need to be considered.

- *Workshops Explaining the Biotechnology Regulatory System*

Local governments would benefit from state-sponsored workshops which explain the regulatory system and the role of the State Task Force. The history of local involvement shows that city and county officials have a limited understanding of the larger regulatory environment in which a particular permit application is being processed. While specific people, such as the county health commissioner or the county agriculture commissioner, may have some contacts within the state's regulatory structure, the lines of communication are not yet established enough to be reliable. Thus, local governments are

not always able to get information to the public quickly and effectively; and consequently public trust can deteriorate. Existing public sensitivity to biotechnology makes clear, timely, and complete information crucial.

Most local governments are unprepared for technical regulation of bioscience.

Strategic Alternatives

Given these conclusions, the ABAG Bioscience Task Force considered the following optional strategies for local regulation of biotechnology activities:

- rely on existing state and federal regulatory mechanisms;
- request that state enact more criteria for field tests;
- adopt local measures now in anticipation of applications involving biotechnology;
- enact ordinances for field testing of new biotechnology products;
- develop substantive local expertise for analyzing the costs and benefits of applications involving biotechnology; and
- concentrate on educating the public about bioindustry benefits and risks

Each Strategy is described below.

- *Rely on Existing State and Federal Regulatory Mechanisms*

Under this scenario development permits would be reviewed as they are submitted; local governments would rely on state and county officials with expertise in biotechnology; no new ordinances or policies requiring special environmental review of biotechnology projects would be adopted; and state and federal permit decisions would only be reviewed by local staff members when requested by local administrators, the Board of Supervisors, or the City Council.

- *Adopt Local Measures Now in Anticipation of Applications Involving Biotechnology*

Adopt measures now to facilitate rapid and standardized information flows when applications are submitted. For example:

1. Localities need to review their existing permit processes in light of state and federal regulations, and to develop standard operating procedures designed to become effective as various types of applications are submitted. These could include:

   a) a list of the staff and elected officials to be notified,

   b) how to notify the public of the application,

   c) how to prepare a staff report which documents the federal and/or state permit decision-making process for the application in question,

   d) how to guarantee local input into state and federal scientific evaluations.

2. Regional workshops and coordination procedure need to be implemented.

   a) Organize regional workshops that would be targeted for county and city officials and that would address the state and federal regulatory system and how each is supposed to interact with local governments. The workshops should also discuss the various types of ordinances that have been passed, the legitimacy of the public's aversion to risk regardless of the scientific and technical review, and how risk assessment can be communicated at public hearings.

   b) Establish a library of biotechnology materials with one person designated as regional coordinator.

   c) Prepare and distribute lists of consultants with expertise in risk communication and biotechnology and State and federal contact persons.

How local governments will decide to handle bioscience regulation will depend on whether they are convinced that state and federal procedures offer adequate protection.

- *Enact Ordinances For Field Testing of New Biotechnology Products*

Adopt local ordinances that either require adherence to specific criteria or environmental review for experimental field tests. The legality of such local regulation is, however, questionable.

- *Develop Substantive Local Expertise for Analyzing the Costs and Benefits of Applications Involving Biotechnology*

Develop expertise at the local level to conduct a cost benefit analysis of proposed biotechnology projects. This alternative would involve County health and agricultural commissioners gearing up their technical staffs or hiring consultants. Conducting risk assessment and cost benefit analysis would require hiring of molecular biologists, ecologists, pathologists, and perhaps even economists. The technical staff would balance risks and benefits and make recommendations to the local government unit and the public.

- *Request That State Enact More Criteria for Field Tests*

Recommend that the state consider enacting more specific criteria for experimental field tests. Such criteria might include minimum buffer zone requirements, airborne material control, and liability mitigation.

- *Concentrate on Educating the Public about Bioindustry's Benefits and Risks*

Focus on ways of improving the public education and comment process on all "significant" biotechnology projects. At a minimum, the program might have three separate elements:

1. An educational element designed to provide correct scientific information in layperson's terms. The technical information could be provided by federal and state officials or applicant representatives. This element must also contain some estimates of benefits.

2. A risk communication element. This part of the process would be designed to put the risks in some perspective with other daily and presumably acceptable risks.

3. A formal comment period. Officials would receive public comments, which would help local governments gain insight on whether perceived risks outweigh benefits or vice versa.

List of Persons Interviewed

Nancy Andrews, Environmental Protection Agency, Region 9
November 6, 1987.

Christine Arneson, California Department of Health Services
November 3, 1987.

John DeFremery, Agricultural Commissioner,
Contra Costa County
November 16, 1987.

Paul Duffey, California Department of Health Services
October 26, 1987.

Wes Ervin, California Department of Commerce
November 2, 1987.

Tobi Jones, California Department of Food and Agriculture
November 13, 1987.

Bob Peterson, Environmental Protection Agency, Region 9
October 30, 1987.

Terry Rivasplata, California Office of Planning and Research
October 16, 1987.

Jim Stratton, California Department of Health Services
November 3, 1987.

Juanell Waldo, Planner, Santa Clara County
November 18, 1987.

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Chapter 7

Bioscience Task Force Meeting Agendas and Minutes

Chapter 7

Bioscience Task Force Meeting Agendas and Minutes

Agenda

Wednesday, August 5, 1987
MetroCenter Auditorium
8th and Oak Streets, Oakland
10:00 a.m. to noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	INTRODUCTIONS
3.0	SPECIAL INVITATION TO REGIONAL PLANNING COMMITTEE MEETING
4.0	BACKGROUND - PURPOSE OF TASK FORCE
5.0	DRAFT GOAL STATEMENT
6.0	SCOPE OF BIOSCIENCES INDUSTRY
7.0	DRAFT WORK PROGRAM
8.0	TASK FORCE STRUCTURE, PROCEDURES AND SCHEDULE

Minutes
August 5, 1987

1.0 Meeting called to order by Chairman Hsieh at 10:15 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)
Supervisor Mary Griffin
Supervisor Tom Powers
Councilmember Dick Spees (President)

Land Use Specialist
Prof. Joseph Sax

University Representatives
Dr. Edward Blakely
Mr. Thomas Rolinson (for David Ramsay)
Dr. Sandra Shotwell (for Mr. Neils J. Reimers)

Scientist
Dr. Selina Bendix

Private Sector
Ms. Martha Bowden
Mr. Brook Byers
Mr. Robert Gorlow
Mr. Zane Gresham
Mr. Richard Love
Mr. Richard Morten
Dr. Charles Webster

ABAG Staff
Mr. Gary Binger, Planning Director
Dr. Raymond Brady, Director, Analysis and Information Services
Mr. Revan Tranter, Executive Director

Members Absent
Ms. Michelle Perrault

2.0 **INTRODUCTIONS**

Chairman Hsieh introduced ABAG staff and each member gave own introduction.

3.0 **SPECIAL INVITATION**

Hsieh extended invitation to Task Force members to attend Regional Planning Committee meeting which would be held at 1:00 p.m. that afternoon. Randy Boris would make slide presentation: New Developments in Medical Technology.

4.0 BACKGROUND

Hsieh gave brief background on establishment of Task Force. It was hoped that it would examine and assess complexity of bioscience activities in Bay Area; develop and recommend certain guidelines for local governmental agencies for their policy-making process; and coordinate and help to expand bioscience activities in Bay Area.

5.0 DRAFT GOAL STATEMENT

Gary Binger, ABAG Planning Director, introduced Proposed Goal Definition. There were various suggestions regarding wording and after some discussion it was decided that Goal Definition would be revised and presented at next meeting on September 2. Spees requested that more proactive statement be added as lead-in which would state the goal as encouraging evolution of biosciences in Bay Area consistent with appropriate protection of public health, safety and the environment. Group agreed on inclusion.

6.0 DEFINITIONAL QUESTIONS: THE SCOPE OF THE BIOSCIENCES INDUSTRY

There was a lengthy discussion by members regarding definition. Brady was requested to revise definition and bring back to Task Force at next meeting. Definition would cover a broader scope of bioscience activity in Bay Area.

7.0 DRAFT WORK STATEMENT

Task Force decided to use the broader definition as basis to conduct whatever research would be appropriate and to provide statement in the form of brief report that dealt with various components of biosciences complex. This would allow Task Force to give staff more direction as to what aspects of that complex it would like to see investigated in more detail.

Spees summed up Work Statement discussion by stating that ABAG hoped Task Force would develop information that would educate the public, especially ABAG's 550 members in local governments, as to what the industry is, what research capabilities are within the universities,

how this finds its way into a variety of activities within Bay Area, and how they affect jurisdictions represented by ABAG. Spees hoped that Task Force and ABAG staff would work cooperatively to bring best to the field in terms of seminars; dissemination of information and variety of other tasks that would get information to public sector; and model-type legislation or other pieces that would be helpful to jurisdictions in dealing with the industry.

Brady will revise Work Program for September meeting to incorporate comments presented by Task Force Members.

8.0 TASK FORCE STRUCTURE, PROCEDURES, SCHEDULE

Tranter indicated that ABAG lacked resources set aside in budget for bioscience study, but would devote as much staff time as possible. He asked if help could be solicited from academia to assist ABAG.

Task Force members indicated various ways in which they could assist ABAG, including some part-time research staff time.

At next meeting Task Force will focus on:

- Revised draft of Goal Statement and Work Statement
- Areas in which Task Force can move ahead
- Who will do what - and when
- Suggested topics for future discussion

Hsieh thanked all members for attending.

9.0 ADJOURNMENT

Meeting adjourned at 12:00 noon. Next meeting: Wednesday, September 2, 10:00 a.m.

The Bioscience Task Force

of the Association of Bay Area Governments

Agenda

Wednesday, September 2, 1987
MetroCenter Auditorium
8th and Oak Streets, Oakland
10 A.M. to Noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES August 5, 1987 meeting
3.0	REVISED TASK FORCE GOAL, DEFINITION OF SCOPE OF BIOSCIENCE AND TASK FORCE WORK TASKS 3.1 Task Force Goal 3.2 Definition of Bioscience Activity 3.3 Task Force Work Program
4.0	PRESENTATION - "REGULATORY AND POLICTICAL FUTURE OF BIOTECHNOLOGY" Richard Harris, Senior Consultant to the Assembly Economic Development and New Technologies Committee of the California State Legislature, will review the status of local, state and federal legislation and its probable effect on future bioscience activities.
5.0	FUTURE AGENDAS The Task Force will be asked to discuss future agendas.
6.0	STATUS OF TECHNICAL AND FINANCIAL SUPPORT FOR ABAG Executive Director Revan Tranter will report on efforts to secure needed resources to support an adequate task force effort. ENCLOSED ARTICLES AND REPORTS "Biotechnology and Governmental Regulation: Overview and Recommendations" Assembly committee report and record of hearing - "The Future of the Biotechnology Industries in California" "Baltimore's Biotechnology Boom", Contra Costa Times editorial

Minutes
September 2, 1987

1.0 Meeting called to order by Chairman Hsieh at 10:10 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)
Supervisor Mary Griffin
Supervisor Tom Powers
Councilmember Dick Spees (President)

Land Use Specialist
Mr. Tom Starrs (for Prof. Joseph Sax)

University Representatives
Dr. Edward Blakely
Mr. Thomas Rolinson (for Dr. David Ramsay)
Mr. Neils J. Reimers

Private Sector
Ms. Martha Bowden
Mr. Brook Byers
Mr. Robert Gorlow
Mr. Zane Gresham
Mr. Richard Love
Mr. Richard Morten
Dr. Charles Webster

ABAG Staff
Mr. Gary Binger, Planning Director
Mr. Revan Tranter, Executive Director

Members Absent
Dr. Selina Bendix
Ms. Michelle Perrault

Others
Carol Copperud - UCSF

Chairman Hsieh introduced ABAG staff and each member gave own introduction.

2.0 **SPECIAL INVITATION**

Hsieh extended invitation to Task Force members to attend Regional Planning Committee meeting which would be held at 1:00 p.m. that afternoon. Randy Boris would make slide presentation: New Developments in Medical Technology.

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Gary Binger, ABAG Planning Director, introduced Proposed Goal Definition. There were various suggestions regarding wording and after some discussion it was decided that Goal Definition would be revised and presented at next meeting on September 2. Spees requested that more proactive statement be added as lead-in which would state the goal as encouraging evolution of biosciences in Bay Area consistent with appropriate protection of public health, safety and the environment. Group agreed on inclusion.

5.0 DEFINITIONAL QUESTIONS: THE SCOPE OF THE BIOSCIENCES INDUSTRY

There was a lengthy discussion by members regarding definition. Brady was requested to revise definition and bring back to Task Force at next meeting. Definition would cover a broader scope of bioscience activity in Bay Area.

6.0 DRAFT WORK STATEMENT

Task Force decided to use broader definition as basis to conduct whatever research would be appropriate and to provide statement in the form of brief report that dealt with various components of biosciences complex. This would allow Task Force to give staff more direction as to what aspects of that complex it would like to see investigated in more detail.

Spees summed up Work Statement discussion by stating that ABAG hoped Task Force would develop information that would educate the public, especially ABAG's 550 members in local governments, as to what

the industry is, what research capabilities are within the universities, how this finds its way into a variety of activities within Bay Area, and how they affect jurisdictions represented by ABAG. Spees hoped that Task Force and ABAG staff would work cooperatively to bring best to the field in terms of seminars; dissemination of information and variety of other tasks that would get information to public sector; and model-type legislation or other pieces that would be helpful to jurisdictions in dealing with the industry.

Brady will revise Work Program for September meeting to incorporate comments presented by Task Force members.

7.0 TASK FORCE STRUCTURE, PROCEDURES, SCHEDULE

Tranter indicated that ABAG lacked resources set aside in budget for bioscience study, but would devote as much staff time as possible. He asked if help could be solicited from academia to assist ABAG.

Task Force members indicated various ways in which they could assist ABAG, including some part-time research staff time.

At next meeting Task Force will focus on:

- Revised draft of Goal Statement and Work Statement
- Areas in which Task Force can move ahead
- Who will do what - and when
- Suggested topics for future discussions

Hsieh thanked all members for attending.

8.0 ADJOURNMENT

Meeting adjourned at 12:00 noon. Next meeting: Wednesday, September 2, 10:00 a.m.

The Bioscience Task Force

of the Association of Bay Area Governments

Agenda

Wednesday, October 7, 1987

MetroCenter Auditorium

8th and Oak Streets, Oakland

10 A.M. to Noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES September 2, 1987 meeting
3.0	"AN OVERVIEW OF INSTITUTIONAL ACTIVITIES IN BIOSCIENCE: EXISTING EFFORTS, FUTURE PLANS AND CONCERNS" Julius Krevans, MD, Chancellor, University of California at San Francisco Neils Reimers, Director, Office of Technology Licensing, Stanford University Daniel Koshland, Professor of Biochemistry, University of California at Berkeley.
4.0	PRELIMINARY INVENTORY OF EXISTING BAY AREA BIOSCIENCE ACTIVITIES Raymond Brady, Manager of ABAG Research and Information Services
5.0	REVISED WORK PROGRAM The Task Force will be asked to approve work tasks based on input from Sept. 2nd meeting.
6.0	STATUS: TASK FORCE FINANCIAL SUPPORT ABAG Planning Director Gary Binger
7.0	NEXT AGENDA The Task Force will identify the primary topic for the next meeting. A preliminary suggestion is to have private bioscience firms report on what they see as opportunities or obstacles for future bioscience activity in the Bay Area.

Minutes
October 7, 1987

1.0 Meeting called to order by Councilmember Dick Spees (presiding for Supervisor Tom Hsieh) at 10:05 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Mary Griffin
Supervisor Tom Powers
Councilmember Dick Spees (President)

University Representatives
Mr. Thomas Rolinson (for David Ramsay)
Mr. Niels J. Reimers

Private Sector
Mr. Brook Byers
Mr. Robert Gorlow
Mr. Richard Love
Mr. Richard Morten
Ms. Michelle Perrault
Dr. Charles Webster
Ms. Sherrie Wilkins

ABAG Staff
Mr. Gary Binger, Planning Director
Dr. Raymond Brady, Director, Analysis & Information Services

Members Absent
Supervisor Tom Hsieh (Chair)
Dr. Selina Bendix
Dr. Edward Blakely
Ms. Martha Bowden
Mr. Zane Gresham
Prof. Joseph Sax

Others
Dr. Julius Krevans - UCSF
Dr. Jeremy Thorner - UC Berkeley

Spees welcomed Michelle Perrault, Environmentalist representative, who was attending her first meeting and there were self introductions around table.

2.0 **APPROVAL OF MINUTES - September 2, 1987**

Approved. M/Griffin/S/Byers/C/. Perrault abstained.

3.0 "AN OVERVIEW OF INSTITUTIONAL ACTIVITIES IN BIOSCIENCE: EXISTING EFFORTS, FUTURE PLANS AND CONCERNS"

Spees introduced Dr. Julis Krevans, Chancellor, University of California at San Francisco. Krevans thanked group for invitation to share ideas and congratulated task force for taking on important issue of biotechnology, which was example of how working together collectively could produce exciting new ideas and opportunities to benefit all communities and the greater society.

Krevans gave overview of what UCSF does and what its presence is in San Francisco, the Bay Area and beyond, especially with respect to biotechnology. He indicated that 800 post-doctoral students (not registered as students and basically supported in a variety of ways other than base support by the State or endowments) were doing extremely important research. Of the 40% from foreign countries, Japan was the largest nation represented. Japan had very conscious and well-financed effort to become major player in biotechnology industry. The competition for slots in research group was very keen. Major universities were supported by society which looked to them as major sources of new ideas to deal with problems of today as well as future. He felt it was important for concerns of general public to be addressed. Krevans said that other communities in U.S. and other countries were working hard to encourage and attract biotechnology ventures. He felt it important for society, and Bay Area to have something exciting to look forward to, and there was an obligation to create a perception and reality that better was yet to come. Promise that bioscience held for better life, whether through better health, better communication, better and cheaper foodstuffs or other things, was important part of what Bioscience Task Force was considering.

Spees introduced Neils Reimers, Director, Office of Technology Licensing at Stanford University. Reimers presented summary overview of bioscience activities at Stanford. The amount of research conducted at the School of Medicine was significant portion of total research conducted at Stanford. In addition to School of Medicine, faculty and students of Department of Biological Sciences in School of Humanities and Sciences conducted Bioscience research. Reimers stated that a major recent initiative in Bioscience at Stanford was the University's Center for Molecular and Genetic Medicine. It would concentrate on Molecular Biology and Molecular Genetics in concert with Medical School and Stanford University Hospital, linking the most advanced

research in these disciplines with teaching and clinical facilities. The direction of Stanford's Bioscience program was to encourage highest scholarship in faculty's exploration of interesting research questions.

Reimers indicated that Stanford had entered into license agreements with Bay Area Bioscience firms. In many cases, there are multiple licenses with them. In relation to Triton Biosciences, Inc., the most important form of technology transfer was the graduated student. In terms of constraints of conducting biomedical research, the environmental impact report procedure had been used to frustrate building programs. A citizens' group, Silicon Valley Coalition, had argued that rDNA research to be performed at new building could endanger public health. These concerns were not limited to the Bay Area but were being experienced throughout the country. Problems in connection with EIRs could be relieved, at least in part, through better public understanding of nature of research to be conducted. Reimers indicated that one way the Task Force could be of help would be the political support from elected officials, perhaps in form of a model ordinance.

Spees introduced final speaker, Dr. Jeremy Thorner, Professor of Biochemistry at U. C. Berkeley and Director of campus-wide graduate training program in Cellular and Molecular Biology (standing in for Professor Daniel Koshland). Thorner presented overview of biological sciences at U. C. Berkeley from closer perspective, that of educating students and actual practice of bioscience. The Cellular and Molecular Biology program at U. C. Berkeley was one of three tied for being largest National Institute of Health-sponsored graduate program. There was one new building on campus devoted to study of bioscience, one under construction, and one to be renovated, all funded in partnership with the State. U. C. Berkeley was somewhat less mission- oriented than UCSF and Stanford, although the three worked closely together. Lawrence Berkeley Laboratory, supported by the Federal Government, was another research arm of the University. It had become more difficult to get Federal funds for research training of students. Biotechnology industry had opened up enormous career opportunities for graduate students trained at U. C. Berkeley. Biggest problem in maintaining biotechnology environment was education, not only of the general public, but in primary and secondary schools that would help students become more enlightened about science. One other area of concern for attracting more biotechnology companies to the Bay Area was availability and affordability of housing. Thorner recommended that Bioscience Task Force be a strong voice in making these concerns known.
There were questions from members of task force after each presenta-

tion. The three institutions seemed to share many things in common, especially the constraints imposed due to lack of information by general public to understand the functions and safety surrounding biotechnology research.

Spees thanked participants for a fine presentation.

4.0 PRELIMINARY INVENTORY OF EXISTING BAY AREA BIOSCIENCE ACTIVITIES

Byers requested that inventory material be reordered and reclassified. He will work with Binger and Brady on format of information.

5.0 REVISED WORK PROGRAM

M/Webster/S/Gorlow/C/to approve revised work program.

6.0 STATUS: TASK FORCE FINANCIAL SUPPORT

Binger reported that letters had been sent to private sector (real estate and development firms) seeking funds for support of bioscience task force activities. The BALANCE FOUNDATION (**B**ay **A**rea **L**eaders **A**ddressing the **C**hallenge of **E**conomy and **E**nvironment) had been established to act as tax exempt recipient of donations. Binger hoped to have financial report at next meeting.

7.0 NEXT AGENDA

The primary topic for discussion at November 4 meeting would be panel discussion comprised of representatives from private bioscience firms. Richard Love (Triton Biosciences, Inc.) would report on experiences of company moving into Bay Area; Sherrie Wilkins (Genentech) would address manpower issues; Martha Bowden (Hewlett Packard) would discuss medical instrumentation and Brook Byers would address the forming of new companies from Bay Area perspective. It was suggested that representative from Chiron Co., Inc. and also manufacturing industry be invited to participate. Binger would send letters of invitation to suggested participants.

Spees indicated that environmental concerns would be addressed at December meeting. Item would be on November 4 agenda to plan format. Michelle Perrault would assist in putting presentation together.

Meeting adjourned at 12:00 noon.

Agenda

Wednesday, November 4, 1987
MetroCenter Auditorium
8th and Oak Streets, Oakland
10 AM To Noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES October 7, 1987 Meeting
3.0	PRELIMINARY INVENTORY OF EXISTING Raymond Brady, Manager of ABAG Research and Information Services
4.0	"AN OVERVIEW OF PRIVATE INDUSTRY ACTIVITIES IN BIOSCIENCE: START UPS AND EXISTING EFFORTS, PLANS FOR THE FUTURE, AND POTENTIAL CONSTRAINTS" A Panel discussion on the dimensions of the industry, interfaces with universities in the Bay Area and suggestions for consideration by the Task Force. Panelists include: Richard Love - Moderator, President, Triton Biosciences Martha Bowden, Product Manager, Hewlett Packard Sherrie Wilkins, Human Resource Generalist, Genentech Inc. Brook Byers, Kleiner, Perkins, Caulfield and Byers
5.0	NEXT AGENDA Michelle Perrault will discuss the content of December's meeting, which will focus on environmental issues and concerns.

Minutes
November 4, 1987

1.0 Meeting called to order by Supervisor Tom Hsieh (chair) at 10:10 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh
Supervisor Mary Griffin
Councilmember Richard Spees (President)

University Representatives
Mr. Thomas Rolinson (for Dr. David Ramsay)
Mr. Niels Reimers

Private Sector
Dr. Selina Bendix
Ms. Martha Bowden
Mr. Stephen Brimhall (for Mr. Ron Cowan)
Mr. Brook Byers
Mr. Zane Gresham
Mr. Richard Love
Mr. Richard Morten
Ms. Michelle Perrault
Ms. Sherrie Wilkins for Mr. Bill Higgins)

ABAG Staff
Mr. Gary Binger, Planning Director
Dr. Raymond Brady, Director, Analysis & Information Services
Mr. Revan Tranter, Executive Director

Members Absent
Dr. Edward Blakely
Mr. Robert Gorlow
Supervisor Tom Powers
Prof. Joseph Sax
Dr. Charles Webster

Others
Ms. Carol Coppersrud - UCSF

2.0 **APPROVAL OF MINUTES - October 7, 1987**

Approved. M/Gresham/S/Griffin/C/.

ANNOUNCEMENTS

Gresham reported that Arthur Young & Co. had completed major survey of biotech companies across the country and had published information and data in Biotech '88 into the Marketplace. Arthur Young staff had indicated willingness to pull out information that might be helpful to

ABAG staff in assessing how Bay Area biotech companies operate; and to make presentation to Bioscience Task Force based on original survey and further manipulation of data that might be appropriate.

3.0 PRELIMINARY INVENTORY OF EXISTING BAY AREA BIOSCIENCE ACTIVITIES

Brady presented revised inventory structure of Bioscience Activity. Staff would do economic analysis of major firms or institutions in Bay Area to determine what was being produced, what selling market was and to whom products were being sold. There would be no identification of firms and at least two in each category would be examined. Byers would make few revisions to inventory structure.

4.0 AN OVERVIEW OF PRIVATE INDUSTRY ACTIVITIES IN BIOSCIENCE: START UPS AND EXISTING EFFORTS, PLANS FOR THE FUTURE, AND POTENTIAL CONSTRAINTS"

A panel discussion was presented on experience of private industry moving into Bay Area, manpower problems in Bay Area and how to form industry in Bay Area. Panelists included:

Richard Love - Moderator President Triton Biosciences	Martha Bowden Product Manager Hewlett-Packard
Brook Byers Partner Kleiner, Perkins, Caulfield & Byers	Sherrie Wilkins Human Resource Generalist Genentech

Love stated that Triton Bioscience was one of largest biotech companies started in last four years. When locating in Bay Area Triton had found it not unduly complicated; City of Alameda had dealt with them both professionally and reasonably. Triton focused on products for treatment and diagnosis of cancer and serious viral diseases. Company, starting with 20 employees in 1984, currently had 175, of whom 80% were degreed professionals. Triton used advanced biology techniques such as genetic engineering to make products, which were in all stages from research to sales. They were still awash in red ink because of long development and approval times required by regulatory bodies.

Some of Triton's business characteristics were that materials were highly contained and regulated at both State and Federal level and everything was done by written procedure. Ties with academia were important; access to university research was strategic to their success. Research universities had been strongly supported by the Federal Government and roughly $4 billion a year was spent on research. In reviewing the pros and cons of Triton's move to the Bay Area, Love indicated that the pros were:

- bioscience research excellence (pioneering nature)
- bioscience community
- great place to live (quality of life)

The cons were:

- expensive
- distance from Washington and regulations
- less community desire for new and more business, and suspicion about technology.

Love recommended that Task Force encourage drive for more fundamental funds for University research, and educate local governments to review existing regulations before adding to already heavy burden.

Wilkins addressed three issues: Genentech and where it had come over last 11 years, costs in biotechnology (time for development and manpower), and issues in biotech as an industry in Bay Area.

Genentech, founded 11 years ago, had played key pioneering role and led field in every aspect. Presently there were 200 Ph.Ds. and 18-20 M.Ds. on staff of 1400 employees. There were 400 people in basic research and development, 200 in quality control and 500 in manufacturing. Of the 500 most were not operators, but were doing research and development. Remainder of employees were in administration and facilities management. Genentech had strong ties with UCSF, UC Berkeley, UC Davis and Stanford, as well as universities throughout U.S. and abroad. Firm had a strong, academically-oriented post-doctoral program. Collaboration with university professionals resulted in further product development and increased funding to both Genentech and the universities. They had extensive educational programs for lay public, students and patients. There was also a scientific program

for those scientists who came to visit and learn more about the industry, and an intern program for graduate and undergraduate students who usually stayed 3 to 4 months.

Biotechnology was big business in terms of health care applications and it took very long time to develop the product. It was about a 10-year process from idea inception to marketplace and generally 3-4 years for basic research, 3-4 years doing clinical trials and 1-2 years for regulatory process. In that period much money went into marketing product, with no income. In 1984 Genentech had 675 employees and spent $66.8 million on expenditures and $55 million on R&D. In 1986 there were 1200 employees with 80% increase in expenditures and $80 million on R&D. In basic research, not including development, 25-30% was used to keep new products coming and keep ties with academia and other partners. Survival of small biotech companies would change radically, with some consolidating, some being acquired by larger pharmaceuticals (mostly on East Coast), some would become contract companies for other biotech companies and some would expand into well- established pharmaceutical companies.

All but 1 to 2% of Genentech's manpower were degreed personnel. Staff were lost by return to school or entry to other fields. Manpower issues were more complex now and recruiting through local newspapers was no longer effective. Genentech was being forced to go outside California to get skilled and new college graduates and relocation costs were extremely high. One answer might be to invest more money in local universities for graduate work in the field. Relocation costs in Bay Area were among highest in country; average of $40,000 to $50,000 was spent to relocate technical person with a family. One of main concerns for future was whether Genentech would be able to keep headquarters facility in Bay Area. Transportation, parking and personnel relocation costs would be major factors as Genentech considered future plans.

Byers, partner in Kleiner, Perkins, Caulfield & Byers, had been in venture capitalist business for about 15 years and personally involved in startup of at least 10 biotech companies. Firm had $360 million capital base with $250 million invested; value of those holdings now exceeded $1.5 billion. The $250 million had been invested in 100 companies in past 15 years, all high tech, 90% in California and rest in Texas and Massachusetts. Byers and partners served on 60 Boards of Directors of those companies. Firm had begun by providing initial funding to Genentech when it started, and next founded Hybritech in

San Diego. That company, acquired by Eli Lily last year, now had 1000 employees. In addition, 12 other biotech companies had been founded, and 7 of 14 were in Bay Area. Most activity has been an San Francisco, San Diego or Boston areas because of ties to UCSF, UC Berkeley, UCSD, Stanford, Harvard and M.I.T. Byers stated some positive factors of startup companies. There was tremendous outflow of research breakthrough now going on. National Institutes of Health had funded over $200 million in research per year in Bay Area just in health care. NIH and universities were becoming more open to working for technology transfer. Scientist and management pools were improving in terms of resources for new companies. Post-doctoral students were increasingly skilled and experienced. At least 2,000 human diseases, acquired or inherited, were poorly treated presently and provided opportunity for further research.

Knowing how to manufacture products once developed was major risk factor facing new companies today. Because of product development cycle, biotech industry had highest requirement for capital needs and availability. Even after years getting to commercial market, product was not always readily accepted by inherently conservative medical community. More venture capital firms were located in Bay Area than anywhere else in world, and capital needs for startup companies were large. At present time it was impossible for biotech companies to go public, which affected ability to raise later amounts to expand manufacturing or sales force. Large corporations were therefore big factor and sometimes partnered with small companies. One of biggest risk factors was in meeting strict regulations required by State and Federal governments. In addition, everything was affected by liability insurance companies who sometimes would not grant liability insurance to small companies because they did not yet understand industry enough to do so.

Byers stated that facility availability in Bay Area was big problem and if given choice he would put new companies in San Diego. In Bay Area his choices would be Alameda, Foster City and South San Francisco because of large industrial parks with available land. San Diego was more enlightened community in terms of building incubation facilities.

He would not locate companies in Berkeley or Palo Alto because those communities did not understand the industry. There was great distrust of science by public in general and ignorance about biotechnology. Biotech industry had not been well organized enough to educate public and communities and attempts were now being made to do so. In terms

of transportation Byers felt that Foster City was central location for people to commute to and from. Bay Area Rapid Transit was not very well developed but nor were transit systems in San Diego and Boston.

Finally, Byers felt that biotech industry was not large employment generator. There were some blue collar jobs, but most were professional and high-salaried. Benefit to communities would be payroll base and high intelligent quotient from high-salaried positions.

Bowden, representing Hewlett-Packard, indicated that company was supplier of analytical instrumentation to biotech industry. Medical products group dealt with critical care and health care monitoring in hospitals, and analytical instrument group with measurement and detection of chemicals and biochemicals. H-P was recognized leader of instrumentation in many different areas. Company would like business and marketing in detection and measurement areas to grow. Much time and money was involved in testing products during both R&D and product and quality control stages. Major emphasis in biotech development was taking place in Palo Alto, although two other substantial sites were in Pennsylvania and in Germany.

Another approach H-P had used to better meet bioscience needs was in developing products internally. They were also looking at licensing technology from universities and Federal labs. Drawback was that most licenses granted were non-exclusive. Some recent government regulations, especially with Federal laboratories, enabled formation of consortiums to take technology from laboratories and bring into industry to enable exclusive licensing. Firm was also looking at developing applications for existing products and how biotechnology could be used in developing detectors in measurement systems. Probably fewer than 50 people world-wide in H-P company were developing products specifically for biotechnology. Some issues that company faced in looking at biotech industry were how to leverage off existing business and sales force. It was difficult for large company to go into new market that was totally incompatible with its sales force. They also needed to leverage existing manufacturing sites and manufacturing processes. Decisions on where to manufacture bioscience products would be based upon compatibility with existing manufacturing capabilities. Access to qualified labor pool was also concern, as well as having resources to hire locally. H-P tried to hire locally as it was so expensive to relocate. There was pressure on companies to manufacture internationally and this was impacted by emphasis countries put on local purchasing. Government regulations were also issue; H-P was not currently major force in clinical instrumentation market mainly because of regulations

involved. Finally, Bowden observed that big-pocket lawsuits discouraged companies in bioscience.

There were questions and answers after each panelist spoke. One area of concern was obtaining information on bioscience work for military application. This seemed to be one area where general public had fear and lack of knowledge. Byers stated he had no general knowledge of any commercial biotech companies doing work in this area and one of the surest ways for new companies to fail was to have safety or other controversial problems. The industry in itself was self-regulating. Hsieh indicated that Task Force would identify concerns and explore ways to be helpful in making information available to local governments as they moved along in bringing issues before the group.

Hsieh expressed appreciation to Tranter and Binger for their support to the Task Force and requested that Binger continue to monitor work program. Funding was still needed to support program and activities of Task Force.

Tranter gave report on fund raising efforts and indicated that so far results had been disappointing. An appeal had been made to foundations and development community and only $1,300 had been raised. He asked Task Force for advice in this effort. Goal was to raise $50,000 to $60,000 for efforts to support Bioscience Task Force and economic development. Efforts would continue as funding was important to keep going. Hsieh urged those members from private industry to give consideration to the fund raising efforts as it was important to continue.

M/Spees/S/Bendix/C/ to write letters to local jurisdictions suggesting any upcoming regulation issues to Bioscience Task Force, in order to bring whatever help and information to them might be available.

The next meeting of the Task Force was set for December 2 [subsequently changed to January 6].

Meeting adjourned at 12:00 noon.

Agenda

Wednesday, January 6, 1988
MetroCenter Auditorium
8th and Oak Streets, Oakland
10:00 a.m. to noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES*
3.0	"AN OVERVIEW OF CONCERNS ABOUT THE ENVIRONMENT" A panel discussion dealing with specific health and safety issues that may require consideration by the Task Force. Moderator-Michelle Perrault Immediate Past President Sierra Club (Task Force Member) Panelists - Walter Truett Anderson, Author, To Govern Evolution: Further Adventures of the Political Animal Andrew Caffrey Co-Director and Founder, Genetic Alert Walter Wong, R.S., M.P.H. Environmental Health Officer, County of Monterey Dr. Margaret Race, Principal Science Policy Analyst, Division of Agriculture and Natural Resources, University of California Dr. Louise Williams Private Consultant (Formerly with California Assembly Office of Research and U.S. Congress Office of Technology Assessment).
4.0	FUTURE AGENDA The next Task Force meeting will focus on: 1. Preliminary findings associated with local regulatory issues affecting bioscience activities, and; 2. Specific work program recommendations developed by ABAG staff and Arthur Young & Co.

Minutes
January 6, 1988

1.0 Meeting called to order by Supervisor Tom Hsieh (chair) at 10:15 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)
Supervisor Mary Griffin
Supervisor Tom Powers
Councilmember Dick Spees
(President)

University Representatives
Dr. Edward Blakely
Dr. David Ramsay
Mr. Neils J. Reimers

ABAG Staff
Mr. Gary Binger
Planning Director
Mr. Revan Tranter
Executive Director

Members Absent
Ms. Martha Bowden

Private Sector
Dr. Selina Bendix
Mr. Brook Byers
Mr. Ronald Cowan
Mr. Robert Gorlow
Mr. Zane Gresham
Dr. C. Bud Colby
(for Mr. Richard Love)
Mr. Richard Morten
Ms. Michelle Perrault
Dr. Charles Webster
Ms. Sherrie Wilkins
for Mr. Bill Higgins)

Others
Mr. Walter Truett Anderson
Mr. Andrew Caffrey
Mr. Walter Wong
Dr. Margaret Race

2.0 **APPROVAL OF MINUTES - November 4, 1987**

Approved. M/Powers/S/Morten/C/.

3.0 **"AN OVERVIEW OF CONCERNS ABOUT THE ENVIRONMENT"**

Hsieh introduced Michelle Perrault, Immediate Past President of the Sierra Club and Bioscience Task Force member, to serve as moderator for panel discussion.

Perrault stated that in putting panel together, major problem was finding representatives from mainstream environmental organizations doing work on biotechnology issue because most were on East Coast. Major groups doing work on the issue were doing so in regulation areas and were just beginning to get into the field. There was, however, a great deal of movement going on in the environmental community. Positions that major environmental groups would eventually arrive at were based on the kinds of work that members on the panel were doing. Some of these were: questions about human genetics and ethics; new organisms and problems over patents; biological weapons and obtaining information about what military was doing in that area; possible reduction of diversity among species; ecological vulnerability; genetic dependence; disclosure; conflict of interest; and regulations. Perrault indicated that public's perception about biotechnology by majority of people polled felt the benefits outweighed risks, but that by a margin of 63% to 26%, those polled said they were more likely to believe environmentalists over the federal agencies.

Perrault expressed regrets that Dr. Louise Williams, Private Consultant and formerly with California Assembly Office of Research and U.S. Congress Office of Technology Assessment, was unable to attend. She introduced the following panelists:

Walter Truett Anderson, Author, To Govern Evolution: Further Adventures of the Political Animal (1987)

Andrew Caffrey
Co-Director and Founder
Genetic Alert

Walter Wong, R.S., M.P.H.
Environmental Health Officer
County of Monterey

Dr. Margaret Race
Principal Science Policy Analyst
Division of Agriculture and Natural Resources
University of California

Anderson had developed a working paper, Governing Biotechnology, that gave overall picture of biotechnology governance issues that dealt with three major areas: safety and regulations, competitiveness and social priorities, which was probably most neglected and most important of the three. He stated that biotechnology was here to stay and would become a political reality throughout our lifetime. It was a fast-moving scientific revolution. The knowledge and techniques that had come out of biotechnology had swept through the life sciences and were transforming them to such an extent that eventually it would become impossible to talk about any field of research that did not involve biotechnology. One of his interests was to see environmental movement get more deeply involved in issues that would reflect its values and thus enhance its credibility. As that happens, there would be more complex set of involvements than merely being opposed to biotechnology. Some of the areas of interest included:

- new approaches to use of biotechnology in developing substitutes for toxic chemicals in agriculture

- development of biotechnology techniques in clean-up of toxic waste

- small-scale applications of biotech for Third World development of bacteria to process organic waste for use in such things as food, fuel, fodder and small-scale economic chemical development.

Anderson found all of these areas to be exciting although the flip side lay in considerations, fears and concerns. Everyone would have to learn more about biotechnology to function in today's society and he hoped quality of media coverage would improve. He expressed appreciation for the work being done by ABAG and Bioscience Task Force.

Caffrey said he would express perhaps the most radical view in opposing genetic engineering. He was active with Earth First, a network of people who had fears that planet was being destroyed, and devoted a great deal of energy in working as opponent and trying to affect policy. He focused on three main points:

- whole context of society's dealing with genetic engineering, both politically and economically;

- advanced genetic sciences and Frostban test as a case study of what might be expected with such tests in the future; and

- citizen involvement in determining whether or not a field test and open release of genetically engineered organism should be done in their backyards.

Caffrey saw some differences in various aspects of genetic engineering. Main concerns focused on organisms that were genetically engineered and released into the open environment to circulate with other organisms on the planet and the use of genetically engineered organisms to manufacture something in a lab—like a drug. He expressed concern with the manner in which companies went into communities to make presentations to gain approval of field testing. He felt that there was not enough information given to general public and that citizens were not allowed to ask pertinent questions. Caffrey stated that his group advocated a 5-year moratorium on environmental tests in local communities. He felt that governmental officials need to realize that there was high level of expertise needed to make sure tests were safe, and it was important that community be allowed to say no to testing if there were doubts. Caffrey concluded by stating that there must be better communication with the general public to educate them on the issues and more protection from the Environmental Protection Agency.

Wong stated that local government must be able to respond to the general public on biotechnology issues. He shared the experience of what had happened in Monterey County last year regarding genetic engineering field testing. The citizens had presented petition to Board of Supervisors two weeks earlier. Board had directed him to explore issue and make recommendations. It was found that testing had been approved by EPA and State Department of Food & Agriculture for Advanced Genetic Scientists to spray in Monterey County but exact location was not revealed. Local government had no authority over biotechnology testing because it was a pesticide; Federal and State government had control over regulatory aspect and permit issuance. It was later found that no field investigation had been made, even though test site was 50 feet from residential area. Major issue was: did local government have authority over outside spraying of genetic engineered micro-organisms? It was found that local government did have land use authority. If all facts had been presented and this fact had been taken into consideration perhaps the situation could have been handled in a different manner.

In April 1987 Monterey County approved first land use ordinance in U.S. regulating the location and siting of experiments involving the release of genetically engineered micro-organisms into the open environment. Wong emphasized that it was not the intent of the ordinance to enter the regulatory sphere occupied by the Federal and State Governments; but to more fully carry out County land use authority embodied in County land use plans and zoning ordinances by using them as primary guides in determining proper location for the conduct of genetic engineering experiments.

Race stated that while talk about biotechnology focused on its impact on health, safety, the environment, consumers, and industry, there was another aspect—the university research communities. Their main concerns were with seeking new knowledge through research and passing it along for people to use. They recognized that with potential changes came problems as not all changes were for the better. Biotechnology had been very carefully scrutinized in the public policy arena and by the scientific community. Discussions had focused on wide variety of issues including:

- laboratory safety and containment
- environment release of genetically engineered products
- adequacy of Federal and State laws
- appropriateness of regulatory mechanisms
- effectiveness of government agencies to carry out the oversight required
- opportunities for public input, involvement and oversight.

Race felt that society had answered these questions by giving biotechnology a green light—without giving up on the yellow and red light when appropriate. General university opinion seemed to be that, as a research community, they should proceed but with caution. There was need for regulatory and legal oversight and university researchers were used to that. There was also a need for an informed and involved public and the university had done all it could to make sure that information was available throughout the Ice Minus conflict. The University's view was that local ordinances imposed financial and logistical demands on

researchers and created an unnecessary additional additional level of review. Their feeling was that court challenge and prompt clarification may be needed to forestall development of unfortunate and unnecessary barriers to promising research. Basically, the University was on record as opposing the Monterey Ordinance.

In conclusion, Race asked that as local government looked at what it should be doing in respect to genetic engineering and biotechnology, the views and concerns of the research community be given consideration.

Researchers were not opposed to regulations, reviews, oversight or permits. It was felt, however, that case by case review of scientific data was important and that to create another level of review to require more permits would stifle research progress.

Panelists gave closing remarks and there were questions and discussion by Task Force Members.

Perrault summed up briefly the topic that Williams would have presented from two recent testimonies. There were 12 major ways improvements were needed, with concerns about potential danger, but control and direction of the industry still remained as major question. There was also difficulty assessing the risks and lack of public experience with technology in general and finally, how evaluations were made in advance of actual implemention.

Hsieh thanked panel for fine job and indicated the ABAG purpose was to assess the information and focus on how it could be beneficial to research programs and helpful to public concerns.

4.0 **FUTURE AGENDA**

Binger reported on meeting held with Arthur Young staff several weeks ago, and thanked Gresham for his part in arranging it. Some staff assistance had been offered to assist Task Force staff in doing some research. Specific work program recommendations developed by ABAG staff and Arthur Young would be presented at future meeting. Staff would report on preliminary findings associated with local regulatory issues at next meeting. There were suggestions for two future agenda topics to include discussion on animal research activities and contained research activities. Binger would put together panels for these items.

Meeting adjourned at 11:50 a.m.

The Bioscience Task Force

of the Association of Bay Area Governments

Agenda

Wednesday, February 3, 1988
MetroCenter Auditorium
8th and Oak Streets, Oakland
10 a.m. to noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES
3.0	SAFETY IN BIOTECH FACILITY DESIGN AND OPERATIONS A presentation on biotech facility design and operation as it relates to safety, the environment, code regulations and review agencies. Steve Copenhagen - McLellan & Copenhagen, Cupertino Russell Palchak - Industrial Health Engineer, Genentech
4.0	BIOTECHNOLOGY REGULATION - LOCAL OPTIONS Staff has prepared a report on existing and future bioscience regulations. The Task force will be asked to review and comment on the findings of the report.
5.0	FUTURE AGENDA TOPICS Upcoming Task Force meetings will cover; A. Regional Biotech Center - Existing plans, future opportunities. B. Status of inventories of economic activity C. Laboratory testing of animals ENCLOSURES A. Program description: UC Davis Biotechnology Program B. San Francisco Chronicle Series

Minutes
February 3, 1988

1.0 Meeting called to order by Supervisor Tom Hsieh (chair) at 10:05 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)
Supervisor Mary Griffin
Supervisor Tom Powers
Councilmember Dick Spees (President)

University Representatives
Dr. David Ramsay & Mr. Tom Rolinson
Mr. Neils J. Reimers

Private Sector
Mr. Zane Gresham
Mr. Richard Love
Mr. Richard Morten
Ms. Michelle Perrault
Dr. Charles Webster

ABAG Staff
Mr. Gary Binger, Planning Director
Mr. Revan Tranter, Executive Director

Members Absent
Dr. Selina Bendix
Dr. Edward Blakely
Mr. Brook Byers
Mr. Ronald Cowan
Mr. Bill Higgins

Others
Mr. Steve Copenhagen
Mr. Russell Palchak

2.0 **APPROVAL OF MINUTES - January 6, 1988**

Approved. M/Webster/S/Bowden/C/.

3.0 SAFETY IN BIOTECH FACILITY DESIGN AND OPERATIONS

Binger thanked Morten for assistance in securing speakers and introduced Steven Copenhagen, Architect, McLellan & Copenhagen, and Russell Palchak, Industrial Health Engineer, Genentech. They were asked to discuss biotech facility design and operations as they related to safety, environment, code regulations and review agencies.

Copenhagen stated that his firm had been designing biotechnology facilities for last 10 to 15 years. Work had started out at university research facilities and evolved to commercial biotech facilities. He focused on design of biotech facilities and safety implications for employees and general public. Architectural process for biotech facilities included normal safety issues associated with uniform building codes, etc., as well as unique state and federal agency requirements. U.S. Food & Drug Administration and Department of Agriculture dealt with exterior environmental effects of biotech facilities: what happened to organisms once they got outside. OSHA regulations focused on health and safety of individuals inside facility and included strict guidelines as to what must be done to both user and environment when handling chemicals and toxic materials. National Institutes of Health published and updated Biosafety and Microbiological & Biomedical Laboratories Journal. The publication defined criteria and base levels of biohazard potentials, defining what organisms go with what biosafety levels and what design standards must be met in operations and facility design. NIH had also published literature on laboratory safety dealing with recombinant DNA. Both reports provided facility design criteria that architects had to respond to in planning and designing biotech facilities. NIH guidelines contained biosafety levels of 1 (least hazardous) through 4 (most hazardous). Determination of biosafety level was dependent upon what organism was being worked with, its hazard level, quantity of organisms and how they were contained. Level 1 was present in almost all laboratories with basically zero hazards, with no special criteria to design to. As levels increased, criteria became more stringent. Procedures also became more defined. When level 3 was reached, containment issues had to be dealt with through gowning, controlled access points, showers and wash facilities, and special controls over waste.

Palchak congratulated Task Force for spending time and resources necessary to become familiar with scientific, regulatory, economic and sometimes emotional issues surrounding biotechnology. His remarks were to focus on worker safety and health programs for employees of rDNA operations, including research, development and manufacturing of protein products in closed facility. He described biosafety, occupational health and medical surveillance programs, and indicated extent to which industry was regulated. He gave examples of how man used biotechnology to manipulate an organism to fit his particular needs—from fermentation of yeast to produce beer to breeding of plants and animals. More recently, rDNA techniques had enabled scientists to move pieces of genetic material from one organism to another. It was standard practice in academic, governmental and industrial labs to transfer genetic material of known functions into simple, benign organisms to get the organism to express a desired trait—which could be production of a protein of choice. Examples of proteins produced today using these methods included human insulin, human growth hormone and TPA (Tissue Plasminogen Activator). Many diseases had been treated effectively through development of such proteins.

Palchak stated that biosafety programs had been developed to meet scientific community's needs, to answer concerns of public and to comply with government regulations. Considerations included both biological and physical containment. Biological containment involved:

(1) preventing certain organisms from interacting harmfully with other organisms,

(2) modifying organism so that it required an exotic nutrient in order to survive, and

(3) preventing organism from invading or infecting other organisms. Physical containment prevented microbial exposure to workers and from release into environment. Facilities, practices and equipment were designed to assure that cultures were tightly controlled. It was in industries' interest to use organisms that posed little risk so as to minimize cost of physical containment facilities. Higher the risk of the organism, higher the cost of physical containment. Also, maintaining sterility of fermentation cultures was required to protect quality of product. Closed contained systems contributed to that goal by preventing invasion of production cultures by other naturally occurring organisms that were all around on daily basis. Industrial hy-

giene programs assisted in limiting potential exposure to chemical agents used in purification operation. Periodic air monitoring programs assured that work practices and equip ment were well-maintained. Chemical waste was carefully collected, neutralized and disposed of.

R&D labs at Genentech were typical of those found in universities and hospitals. There were over 100 labs there and one lab was at biosafety level 2 while all the rest were at level 1. Low-level radio-active materials were used in experiments in labs as molecular tracers. Procedures for monitoring radio-activity and properly disposing of isotopes were used. Medical surveillance programs provided for routine physical exams, job histories and bioassays for early detection of illness. Data was collected for rDNA worker groups and compared to groups of non-rDNA employees. This assisted in early detection of differences or trends in health of rDNA employees.

Palchak spoke about regulatory environment in which Genentech operated. At Federal level they were regulated by National Institutes of Health, Food & Drug Administration, Environmental Protection Agency, National Institutes for Occupational Safety & Health, Occupational Safety & Health Administration, Nuclear Regulatory Commission, and U.S. Dept. of Agriculture. At State level they were regulated by Toxics Substance Control Division, Dept. of Health Services, and the Radiological Health Branch. Local level regulators included County Health Department, local publicly-owned treatment works for effluent and sewage, Bay Area Air Quality Management District, Regional Water Quality Control Board and local fire department. Biotech industry was also uniquely self-reviewing. Institutional biosafety committees were made up of at least five members, each with expertise in rDNA technology. Minimum of two of the five were not affiliated with the institution, and represented the interest of surrounding communities. Institutional biosafety committees were responsible for reviewing all projects for compliance with NIH guidelines and providing independent assessment of facilities, procedures and practices and training of rDNA employees.

In summary, Palchak stated that industry existed in dynamic, heavily regulated, environment. OSHA had published statement in Federal Register on April 12, 1984 stating "The Occupational Safety & Health Act of 1970 provides an adequate and enforceable basis for protecting the safety and health of employees in the field of biotechnology and no additional regulation is necessary."

There was question and answer period by members of Task Force and general public.

4.0 BIOTECHNOLOGY REGULATION - LOCAL OPTIONS

Staff had prepared report on existing and future bioscience regulations. Hsieh stated that Task Force had been fortunate that local media had given attention to what ABAG was doing. On the other hand he called to group's attention that previous day's article in San Francisco Chronicle suggested that Task Force had reviewed report and concurred with opinion. This was not the case and he hoped that in future this would not happen. Binger introduced Maria Ray, who had been instrumental in putting report together, and highlighted some conclusions reached in report.

Federal Regulatory Framework reviews were on case-by-case basis which allowed for flexibility and more focus on specific type proposals. It seemed highly unlikely that any new product would slip through the cracks in review process. State Regulatory Framework also processed permits on case-by-case basis and complemented Federal review. There were contact resources available, particularly at Departments of Health Services and Agriculture.

Binger indicated that staff had concluded that although system was a good one, lines of communication with local government could be improved. Staff had determined more could be done in early notification and education of community in regard to proposals in area of deliberate release. Local governments were drawn into the experimental field tests and to some new university biotech facility proposals.

Binger presented range of options for consideration and discussion, not meant to be all inclusive or taken as firm recommendations.

Staff recommended improvements in information flow between the state and local communities, possibility of more specific criteria for deliberate release tests, and ways of improving public education and early involvement in significant new projects.

After discussion by Task Force and questions from general public, Hsieh requested that staff combine comments and suggestions and bring to future meeting revised recommendations. Binger felt it might be appropriate to invite people from State regulatory agencies for presentation at next meeting.

Binger announced topics for future agendas which included:

A. Regional Biotech Center - Existing plans, future opportunities.

B. Inventories of economic activity.

C. Laboratory testing of animals.

Meeting adjourned at 11:55 a.m.

The Bioscience Task Force

of the Association of Bay Area Governments

Agenda

Wednesday, March 9, 1988
MetroCenter Auditorium
8th and Oak Streets, Oakland
10 a.m. to noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES
3.0	ANIMAL TESTING IN BIOSCIENCE RESEARCH - AREAS OF CONCERN In response to task force direction, an animal rights panel will present the concerns of the animal rights community about biotechnology and the use of animals in biotech-research.
4.0	STATE REGULATION OF BIOSCIENCE A panel of state officials will address the task force on issues relating to permit processing and community involvement with a focus on deliberate release projects. Speakers include: • Wes Ervin - Project Coordinator - Biotechnology - Department of Commerce • Tobi Jones - Chief of Pesticide Registration Branch - Department of Food and Agriculture • Paul Duffey - Research Microbiologist - Department of Health Services
5.0	STATUS REPORT/FUTURE DIRECTIONS Staff has prepared a brief summary of accomplishments to date along with recommended future task force focus.
6.0	ENCLOSURES A. Comments on staff report re bioscience regulations - Triton Biosciences Inc. (Dick Love) and CIBA (Brian Sway) B. Miscellaneous articles

Minutes
March 9, 1988

1.0 Meeting called to order by Supervisor Tom Hsieh (chair) at 10:10 a.m. at MetroCenter, Oakland. The following members and staff president:

ABAG Executive Board
Supervisor Tom Hsieh
(Chair)
Supervisor Mary Griffin
Supervisor Tom Powers
Councilmember Dick Spees
(President)

University Representatives
Dr. David Ramsay &
Mr. Tom Rolinson
Mr. Neils J. Reimers

ABAG Staff
Mr. Gary Binger,
Planning Director
Mr. Revan Tranter,
Executive Director

Private Sector
Ms. Martha Bowden
Mr. Robert Gorlow
Mr. Zane Gresham
Mr. Colby
Mr. Richard Morten
Ms. Michelle Perrault
Dr. Charles Webster
Mr. Steven Wade

Others
Mr. Steve Sapontizis
Ms. Joyce Tishler

2.0 **APPROVAL OF MINUTES - February 3, 1988**

Approved.

3.0 **ANIMAL TESTING IN BIOSCIENCE RESEARCH - AREAS OF CONCERN**

Hsieh stated that special effort was made to schedule a panel to discuss issue of animal rights.

Binger thanked Ellen Bring, who initiated panel discussion idea and assisted in securing speakers, and introduced Joyce Tishler, Executive Director Animal League Defense Fund and Steve Sapontizis, philosophy Professor at California State Hayward. Binger advised Task Force that Ellen Bring supplied copies of the book, "Beyond the Laboratory Door", and members interested could have a copy.

Sapontizis stated he would address two issues in his presentation; the philosophy of Animal Rights and public oversight on animal research.

Sapontizis stated that he was pleased with goals adopted by Bioscience Task Force, and recommended that humane treatment of animals be added.

He advised fact that animals did not become a concern of civic leaders and the public until 19th century. Most of the animal rights legislation rallied for were by same people who initiated reform for industrial workers, children and women. The 19th Century attitude was to be kind to animals; it was all right to use them but not to inflict unnecessary pain. This movement originated the term "Animal Welfare". In 1970's a new wave of thinking began and the term "Animal Rights Movement" originated. The difference between these two movements relates to being kind and being fair to animals.

Sapontizis stated that public oversight on Animal Care Committee's has been a constant battle for the movement, being opposed by industries that produce animal research equipment and medical organizations who use animals for research. He stressed need for public control in biomedical research and asked ABAG do what ever it can to incorporate local regulations into the humane treatment of animals.

Joyce Tishler, Executive Director of the Animal League Defense Fund addressed Task Force both as an Animal Right's advocate and as a lawyer.

She voiced public concern over engineering of wildlife species to withstand acid rain, and to resist pollution which would eventually drive out the natural species. Another concern is the patenting of farm animals. She stated that the farming system has become very industrialized and has caused animals to survive in small cramped quarters, getting little or no sunlight and kept constantly pregnant for most of their adult lives.

Tishler raised the question of patenting. Recent decisions by the Supreme Court to allow patenting of scientifically engineered micro-organisms has set precedent for scientifically engineered animals. This would in turn cause more abuse and pain for animals.

In closing Tishler stated that any endorsement of a biotechnolgy committee should also include an advisory committee with animal rights representation on it.

Powers asked if there were any publications that could aid in the determination of what is ethical for lab animals. Tishler responded that National Institute of Health Guidelines for the Care and Treatment of animals does address these issues with some good and some not-so-good information.

The Task Force questioned the term "rights" in connection with animals, and asked what the extent should be. Tishler responded that animals should be able to be represented by those who have their best interest in mind against those who don't.

4.0 STATE REGULATIONS OF BIOSCIENCE

Chairman Hsieh introduced Wes Ervin, Project Coordinator of Biotechnology for the State Department of Commerce, to address Task Force on State regulations effecting the bioscience industry.

The California Inter-Agency Task Force on Biotechnolgy, created by Executive Order, first task identified duplications and gaps in the state and federal regulatory programs as they related to biotechnolgy. They chose to look at the products being produced to determine the kind of approach to regulations.

Paul Duffey, Research Microbiologist for the Department of Health Services addressed Task Force on laboratory safety and risks from microbes. He described five points of microbiological safety as: (1) proper training, (2) proper supervising of people who work with micro-organisms, (3) institutions should have a set of enforceable safety mechanisms, (4) availability of safety equipment and (5) laboratory should be designed for the type of micro-organism being worked on. He stated there is no known occurrence of an accident in a laboratory; industrial, research, or medical in this country resulting in an outbreak of disease in community.

He told Task Force members that there is a bio-hazard classification to determine how risky the micro-organisms are to work with. Laboratories are inspected to ensure that safety precautions are being followed before federal grants are approved. NIH will visit each facility before it is approved for classification level three or four, and will make periodic checks of facilities after they are approved.

Tobi Jones - Chief of Pesticide Registration Branch - Department of Food and Agriculture reviewed Ice Minus Experiment in Brentwood and the A Pesticide Regulatory Programs. Focus was on the Pesticide Regulatory Program within the Dept. of Food and Agriculture, Division of Pest Management. Within this program is the biotechnology working group. It was formed in 1984 as an ad hoc group put together to discuss issues of the use of recombinant DNA technology in pesticides. It is composed of staff scientists from 5 of the 6 branches of department. It reviews experiments of proposed releases of genetically engineered micro-organisms and is involved in assessing risk. Risk assessment of genetically engineered micro-organisms at this stage this is not a quantitative process. The risks associated with micro-organisms are different than usage of chemicals. The form in which risk assessment takes place now is based on asking a series of questions about micro-organisms themselves. They are interested in the characteristics of the organism. What does that organism look like relative to other organisms, how does one identify it? The total number of organisms to be used also is of interest. What kind of plant and animal communities surround that particular experimental site and climatic considerations is taken into account relative to a proposed experiment. Other environmental effects considered include water quality, ecological disruption potential, and weather effects and lastly an evaluation of experimental procedures.

Jones described process that EPA goes through. They first take a look and develop a set of questions, convene a panel of scientists representing areas of concern; be it microbial ecology, plant pathology, etc., and consult with those scientists in the assessment of risk. If the agency determines that experimental use permit is needed, they determine need for additional data and consult with scientists from other federal agencies who may be interested or who may have concerns about the use of organism. At present time, EPA will probably cause an experimental use permit to be issued for any experiment with a genetically engineered micro-organism. Also, very important in assessment of risk is the State's Pesticide Registration and Evaluation Committee. This

committee is an inter-agency committee composed of state agencies that consult with the Department on pesticide-related matters. Staff scientists from other state agencies then have opportunity to review proposed experiment. The final decision is made within the Dept. of Food & Agriculture by program managers within Pesticide Regulatory Program.

In endeavoring to provide continuing input to Counties on biotechnology issues, the Department has increased awareness of County Agricultural Commissioners on biotechnology issues.

5.0 STATUS REPORTS/FUTURE DIRECTIONS

The Task Force agreed to establish working groups on specialized subject areas. These groups would investigate and bring back recommendations to the full Task Force.

Meeting adjourned at 12:00 Noon.

Agenda

Wednesday, June 1, 1988
Joseph P. Bort MetroCenter Auditorium
8th and Oak Streets, Oakland
10:00 a.m. - 12 Noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES
3.0	PUBLIC CONCERNS AND LOCAL REGULATIONS The Task Force's working group is submitting its recommendations.
4.0	PUBLIC EDUCATION AND PROMOTION The Task Force's working group is submitting its recommendations.
5.0	BIOSCIENCE RESEARCH PROGRAMS AND RESOURCES OF BAY AREA MAJOR UNIVERSITIES Staff has completed analysis of above subject for consideration and acceptance by the Task Force.
6.0	ECONOMIC INVENTORY: PRELIMINARY FINDINGS Staff is nearing completion on identifying the extent and economic potential of Bay Area bioscience activity.
7.0	ADJOURN
	MISCELLANEOUS ARTICLES AND INFORMATION ENCLOSED.

Minutes
June 1, 1988

1.0 Meeting called to order by Supervisor Tom Hsieh (chair) at 10:15 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)
Supervisor Mary Griffin

University Representatives
Dr. David Ramsay
Mr. Niels J. Reimers

Private Sector
Mr. Stephen Brimhall for
Mr. Ron Cowan
Dr. John Cole for
Mr. Richard Love
Mr. Robert Gorlow
Mr. Zane Gresham
Mr. Richard Morten
Ms. Michelle Perrault

ABAG Staff
Mr. Gary Binger, Planning Director
Dr. Raymond Brady, Director,
Analysis & Information Services
Dr. Chin Ming Yang,
Senior Systems Analyst

Members Absent
Dr. Selina Bendix
Dr. Edward Blakely
Ms. Martha Bowden
Mr. Brook Byers
Supervisor Tom Powers
Councilmember Dick Spees
(ABAG President)
Dr. Charles Webster

2.0 **APPROVAL OF MINUTES - March 9, 1988**

Approved. M/Gresham/S/Griffin/C/.

3.0 PUBLIC CONCERNS AND LOCAL REGULATIONS

Binger noted that Task Force had established working group focusing on public concerns and local regulations related to bioscience activities. Participants had included Supervisors Tom Hsieh and Mary Griffin, Dick Morton, Charles Webster, Dick Love and Zane Gresham. He summarized group's specific recommendations for consideration and action.

M/Morten/S/Gorlow/C/ to substitute language under Bioscience companies (item 2) to read:

Management & staff should continue to support and implement State and Federal regulations governing research, development, manufacturing, distribution and disposal of bioscience materials and products.

M//Gresham/S/Reimers/C/ to change text under Local governments (opening paragraph) to read:

Prior to considering local regulation of biotechnology, local governments should understand the extensive existing State and Federal system for regulation of biotechnology activities and the opportunities which this system provides for local participation.

M/Gresham/S/Perrault/C/ to substitute language under Local governments (item 3) to read:

Be aware of the potential liability in locally regulating biotech activity. If a local government does adopt a regulation and inspection program, it must then carry it out completely. If if does not, and some harm results, the local jurisdiction could become liable for the harm.

M/Morton/S/Griffin/C/ to substitute language under Local governments (item 4) to read:

In order to minimize unnecessary delay and confusion, local zoning should be made clear, in advance, about where office and laboratory space related to bioscience activity is encouraged.

M/Hsieh/S/Reimers/C/ to add an item 6 under State and Federal governments to read:
Conduct periodic workshops or seminars with local and regional agencies on a regular basis about regulatory and scientific issues relating to bioscience activity.

M/Griffin/S/Gresham/C/ to accept working paper.

Hsieh stated that the working paper would be presented to the Executive Board at June 16 meeting for review and comments.

4.0 PUBLIC EDUCATION AND PROMOTION

Binger noted that Task Force had established working group focusing on ways of improving public awareness and promoting bioscience activity in the Bay Area. Participants had included Supervisors Tom Hsieh and Mary Griffin, Dick Morton, David Ramsay and John Cole. He summarized group's recommendations for consideration and action.

Morton indicated that bioscience center would serve as regional resource center.

M/Gresham/S/Morton/C/ to restate description of bioscience on page 2.

M/Gresham/S/Cole/C/ to accept working paper.

5.0 BIOSCIENCE RESEARCH PROGRAMS AND RESOURCES OF BAY AREA MAJOR UNIVERSITIES

Dr. Chin Ming Yang presented results of a survey on bioscience research programs and resources of Bay Area major universities. Report sampled bioscience research activities at University of California, Berkeley, University of California, San Francisco, and Stanford University in terms of programs and resources; collaborations with researchers of other institutions and researchers of bioscience industries; and existing and future public education and awareness programs. Survey not intended to be exhaustive but to be sampling of research at these universities. Summary was broken down in the following categories:

- Research funding
- Significance of bioscience research
- Research facilities
- Training
- Prospects for commercialization
- Collaborations
- Technology transfer
- Industrial support
- Concerns and constraints
- Recommendations from researchers to ABAG's Task Force

Report concluded that universities offer essential resources to the developing bioscience industry and are available to support Bay Area governments in making rational decisions with regard to promotion and regulation of bioscience industries. As a valuable resource, university bioscience activities in the region needed to be preserved, protected and developed with great care. ABAG could be facilitator and clearinghouse for regional bioscience industrial development programs, policies and regulations and through those efforts bioscience industrial development could be an important part of a regional economic development plan.

6.0 ECONOMIC INVENTORY: PRELIMINARY FINDINGS

Dr. Raymond Brady presented report on the Bay Area bioindustry economic overview. Report classified bioindustry into two components: research, production or commercialization of biological or chemical processes, and physics and materials technology used to support biotechnology. The data analyzed, while still limited, showed extent of economic activity in the Bay Area. Although industry was popularized as an "emerging industry," the facts indicated that it was well established in Bay Area and continues to expand in importance as source of employment, wealth creation and knowledge production. Given large number of firms focusing on biotechnology and material technology, a market adjustment would probably occur which would either drive substantial number of firms out of market or result in consolidation into larger firms. Given instability of market and research environment, it was essential that public policy provide consistent and well defined rules and regulations governing public aspects of the industry. Report suggested that the industry had substantial economic potential and would reinforce economic strength of high tech industry, specific small non-biotechnology manufacturing activity and business services and finance industries in the Bay Area. After questions and discussion, it was indicated that Brady's final report would be brought to Task Force for consideration.

Hsieh announced that the animal issue would be discussed at July 6 meeting and that staff would prepare summaries of what the Task Force has accomplished to date.

Meeting adjourned at 12:00 noon.

The Bioscience Task Force

of the Association of Bay Area Governments

Agenda

Wednesday, July 6, 1988

Joseph P. Bort MetroCenter Auditorium

8th and Oak Streets, Oakland

10:00 a.m. - 12:00 Noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES
3.0	FINAL REVISIONS - TASK FORCE RECOMMENDATIONS RE: PUBLIC EDUCATION AND PROMOTION Staff suggests the preliminary Task Force recommendations be amended by adding two specific implementation actions.
4.0	FINAL REVISIONS - TASK FORCE RECOMMENDATIONS RE: PUBLIC CONCERNS AND REGULATIONS The ABAG Executive Board asked the Task Force to consider some rewording of its preliminary recommendations.
5.0	ANIMAL USAGE Persons and organizations familiar with animal use in bioscience research were asked to provide certain information to the Task Force. The purpose of this information is to assist in any formulation of recommendations regarding animal usage associated with bioscience activities.
6.0	FINAL PRODUCTS OF TASK FORCE Chairman Hsieh suggested that the Task Force consider possible final products of the effort.
7.0	UNIVERSITY BIOSCIENCE RESEARCH STAFF AND FUNDING At the last monthly ABAG's Bioscience Task Force meeting, staff made a brief presentation on the draft report Bioscience Research Programs and Resources of Bay Area Major Universities.

Minutes
July 6, 1988

1.0 **Meeting** called to order by Supervisor Tom Hsieh (chair) at 10:10 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)
Supervisor Mary Griffin
Supervisor Tom Powers

University Representatives
Mr. Tom Rolinson
for Dr. David Ramsay
Mr. Niels J. Reimers

Private Sector
Dr. Selina Bendix
Mr. Robert Gorlow
Ms. Michelle Perrault

ABAG Staff
Mr. Gary Binger, Planning Director

Members Absent
Dr. Edward Blakely
Ms. Martha Bowden
Mr. Brook Byers
Mr. Zane Gresham
Mr. Richard Morten
Supervisor Tom Powers
Councilmember Dick Spees,
ABAG President
Dr. Charles Webster

Hsieh acknowledged and thanked David Field, Vice President - Biomedical Research, Children's Hospital, for providing special survey on independent research institutions

2.0 **APPROVAL OF MINUTES - June 1, 1988**

Approved. M/Griffin/S/Reimers/C/.

3.0 **PUBLIC CONCERNS AND LOCAL REGULATIONS**

Binger requested Task Force approve two amendments to Public Education and Promotion recommendations as follows:

1) A workshop to publicize conclusions of the Task Force, to be held in the Fall, open to the public.
2) That the newly created Bay Area Economic Forum consider focus ing on ways to formally implement Task Force recommendations.

M/Bendix/S/Gorlow/C/.

4.0 **FINAL REVISIONS - TASK FORCE RECOMMENDATIONS RE: PUBLIC CONCERNS AND REGULATIONS**

Binger stated that ABAG Executive Board had asked Task Force to consider some rewording of its preliminary recommendations and staff had responded to request. Binger requested Task Force approval of modified recommendations.

M/Powers/S/Griffin/C/.

5.0 **ANIMAL USAGE**

Hsieh stated that request for information had been mailed to about 30 individuals and groups, and material had been received from a total of five. He introduced following three speakers to address issues of animal usage:

- Helen McCloskey, President of Palo Alto Humane Society
- Michael Endicott, Citizens for Life, Education& Research (CLEAR)
- Sandra Bressler, Executive Director of California Biomedical Research Association

McCloskey referred to rebuttal to Stanford University President Donald Kennedy's Oct. 29 article in Wall St. Journal and material was handed out to Task Force members. She asked members to consider some specific and positive statements as they formulated policies on biotechnology regarding use of animals in research. There were three major statements:

1. Support community representation on animal use committees. Such representation to include input of community, including Humane Society and other animal welfare organizations, to insure that community representative was acceptable to those interested in and concerned with welfare of animals.

2. Support humane care of laboratory animals and the intent of 1985 Amendments to the Animal Welfare Act passed by U.S. Congress in December of 1985. The implementing regulations for those improvements in laboratory housing and care had still not been issued in final form.

3. Support efforts to advance research technologies to replace or lessen use of animals in research.

Endicott stated that, as in past years, animals continued to play vital role in research. Animal use issues were often clouded by sensationalism and emotional appeal. Members of CLEAR were dedicated to examining claims made by looking at all sides of issues. He felt it was important for local governments to understand issues and support appropriate regulations as they occurred. Treatment of many diseases today were result of animal research and it was essential to continue animal use in order to prevent bankruptcy of health care systems. General public was affected because their health care was being affected by decisions made in research. Endicott urged Task Force to support and educate local governments on issues involved in quality of treatment of animal and human care in research, and to select representatives for animal use committees who would contribute in open and positive manner.

Bressler stated that use of animals in research was heavily regulated at federal, state and institutional levels. Animals used for bioscience were covered by same laws and regulations as animals used in any other research. She felt there was no need for additional local government regulation of animal care and use as this could drive researchers and industry out of those communities. Even before required by law, many institutions who used animals had animal use committees. She encouraged education of local governments about need to use animals in research and suggested that representatives visit facilities to learn what was taking place. She also thought it useful to have representatives on animal care and use committees who expressed views of the communities represented. It was important that committees demand that animals be used humanely. There was one additional speaker from the audience, Marti Kheel, animal rights activist.

Kheel stated that use of animals was very dangerous kind of research. She felt there seemed to be warfare mentality towards research, and suffering by animals was overlooked. Kheel felt there should be more emphasis on major causes of disease with regard to lifestyles and the environment. Kheel also advised that many theologians, philosophers and scientists questioned use of animals in research and she urged Task Force to encourage more research by clinical studies, rather than living creatures.

Discussion was opened to Task Force members and following suggestions were made:

Powers - Formulate recommendation after public discussion in local jurisdictions; consider all viewpoints and best possible way to come up with solutions. Be clear about specific guidelines and focus on major things local government could look at.

Hsieh - Balance must be created by research institutions and community. Task Force should show leadership, but not tell local government what to do.

Griffin - It would be helpful to encourage that ALAC standard be used as guide.

Rolinson - Take look at existing regulations. Bioscience research does use animals and about 80% are rodents.

Bendix - Task Force decision on animal use should be made public as information sharing item.

Hsieh concluded discussion by requesting that staff prepare draft statement/recommendations directed to local jurisdictions.

6.0 **FINAL PRODUCTS OF TASK FORCE**

Binger advised that final outcome of Task Force effort would include:

1. Final report including information provided as well as Task Force recommendations.

2. Workshop for public officials on Task Force findings and recommendations.

3. Summary paper to be distributed to local governments dependent on financial support for its preparation.

There will be no meeting in August and the September 7th meeting would probably conclude the formal Task Force work.

Meeting adjourned at 11:30 a.m.

Final Agenda

Wednesday, September 7th, 1988
Joseph P. Bort MetroCenter Auditorium
8th and Oak Streets, Oakland
10:00 a.m. to Noon

Item Number	Topic
1.0	CALL TO ORDER
2.0	APPROVAL OF MINUTES
3.0	ANIMAL USE IN BIOSCIENCE RESEARCH Persons and organizations familiar with animal use in bioscience research have provided information to the Task Force. The Task Force will now consider stating a position on this matter.
4.0	BIOSCIENCE RESEARCH AT UC DAVIS Chin Ming Yang will summarize research activities and opinions of bioscience researchers at the University of California, Davis.
5.0	SUMMARY OF TASK FORCE WORK Chairman Hsieh will provide an overview of what the Task Force has accomplished and what is to happen with information and recommendations that have been developed. Creation of ad hoc small working groups to implement recommendations will be discussed. Included are the committee's findings and recommendations as they have been summarized for the final report.
6.0	WORKSHOP ON BIOSCIENCE FOR LOCAL OFFICIALS The preliminary concept for the workshop will be presented.
7.0	FINAL ADJOURNMENT

Minutes
September 7, 1988

1.0 Meeting called to order by Supervisor Tom Hsieh (chair) at 10:15 a.m. at MetroCenter, Oakland. Following members and staff present:

ABAG Executive Board
Supervisor Tom Hsieh (Chair)

Supervisor Tom Powers

University Representatives
Ms. Carol Copperud for
Dr. David Ramsay
Mr. Niels J. Reimers

Private Sector
Dr. Selina Bendix
Dr. John Cole for Mr. Richard Love
Mr. Zane Gresham
Mr. Richard Morten
Ms. Michelle Perrault
Mr. Bob Polzoni for Mr. Ron Cowan

ABAG Staff
Mr. Gary Binger,
Planning Director
Dr. Chin Ming Yang

Members Absent
Dr. Edward Blakely,
Ms. Martha Bowden
Mr. Brook Byers
Supervisor Mary Griffin
Councilmember Dick Spees
(ABAG President)
Dr. Charles Webster

2.0 **APPROVAL OF MINUTES** - July 6, 1988

Approved as corrected. M/Gresham/S/Bendix/C/.

3.0 **ANIMAL USE IN BIOSCIENCE RESEARCH**

Binger reported staff's recommendations on use of animals in bioscience research for adoption by Task Force. Recommendations focused on public concerns such as humane animal treatment during research and requirements of an emerging industry which could contribute to continued economic prosperity of Bay Area residents.

Bendix complimented Binger on excellent job of formulating reasonable recommendations that reflected concerns of many different points of view.

Hsieh stated that animal issue was very difficult to address because of the different interest groups, with varying levels of concern, but felt it important to strike a balance in order to have everything go forward. If that did not happen, the bioscience industry and research would suffer. He invited comments from Task Force members.

Task Force members discussed the draft language and the following motions were made:

M/Morten/S/Gresham/C/ to amend language under Recommendations to Local Government, item 1, to read as follows:

Before adopting unique regulations, local government should recognize and understand the (substantial and comprehensive) system of federal and state regulations governing the humane care and use of laboratory animals, to determine whether or not the existing regulatory framework is deficient in meeting local needs, and communicate their concerns through ABAG to the appropriate regulatory body.

M/Gresham/S/Cole/C/ to change language under Recommendations to Bioscience Companies and University Researchers, item 3, to read as follows:

When animals are to be used for research, adherence to standards developed by the National Academy of Sciences for the National Institutes of Health and which are used by the American Association for Accreditation of Laboratory Animal Care (AAALAC) is preferred, particularly for large companies and educational institutions.

M/Gresham/S/Powers/C/ to accept recommendations by staff on draft proposal, subject to amendments to be circulated at end of meeting.

4.0 BIOSCIENCE RESEARCH AT UC DAVIS

Dr. Chin Ming Yang reported on survey he conducted at UC Davis with four faculty members, two plant and two animal science researchers. Their general comments were similar to those of other three universities, UC Berkeley, UCSF and Stanford, but there were some differences. The training program at UC Davis was more theoretical and their agriculture department ranked number two in the nation, last year, behind Cornell University. They received strong industrial and non-monetary support

for research programs. There was very little bench space for students and post-doctoral researchers, and it had become very crowded for some faculty. Many agricultural applications, both in plant and animal sciences, had been applied commercially and they held great prospects for the future.

UC Davis' University Agricultural Extension Service had been identified as an effective network to transfer newly-developed bioscience technology to farmers and producers. Security measures and public concerns increased research and animal procurement costs. Faculty members had recommended that ABAG member governments take into consideration the inherent changing and evolving characteristics when designing policies and regulations.

5.0 SUMMARY OF TASK FORCE WORK

Hsieh stated that in order to provide a healthy and good future for Bioscience, ABAG had taken leadership role to ensure that local government would understand potential impact of bioscience activities. Task Force considered research and institutional activities, regulatory implementation as well as other public and industry concerns. In Bay Area alone, from 1985-87 bioindustry revenues grew 52% and employment 32%. The Bay Area had become one of the finest and most important biosciences centers in the country.

Report provided by staff highlighted some of the concerns that had been presented to Task Force over last 12 months. Hsieh personally thanked members of Task Force who had taken on the assignment. He stated that this was only the beginning and ABAG could look forward to two major items, a November workshop (date and location to be determined) and upon completion of last meeting, a report would be issued on Task Force activities. He commended Binger and staff for very fine job and support provided.

Binger gave summary of Task Force effort. A report was scheduled for release in mid to late September. Each Task Force member would be provided a complimentary copy. Binger asked for final comments on summary.

After discussion of amendments and suggested changes by Task Force members, a recess was taken to allow staff time to compile and rewrite changes.

After recess meeting reconvened and Binger reviewed proposed changes in section on Recommendations to Local Governments.

M/Gresham/S/Reimers to accept these additional amendments in section under various items.

M/Perrault/S/Morten/C/ to refine language under Recommendations to Local Governments, item 1, to read as follows:

Before adopting unique local regulations, local governments should consider the existing federal and state regulations governing the humane care and use of laboratory animals, determine whether or not the existing regulatory framework is deficient in meeting local needs, and communicate their concerns to the appropriate regulatory body. Local governments sharing similar concerns are encouraged to forward their communications through an organization such as ABAG.

M/Gresham/S/Perrault/C/ to accept additional amendments to recommendations to Bioscience Companies and University Researchers, item 1, to read as follows:

Be aware that, in addition to the issue of the humane treatment of animals, animal rights advocates have significant concerns regarding the legal and ethical implications of patenting or other uses of life forms that may be the result of such research.

Gresham acknowledged Chairman Hsieh's fine leadership and fairness in conducting the Task Force meetings and expressed opportunity to work with members of Task Force on other occasions. Members responded with round of applause.

Meeting adjourned at 11:50 a.m.

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ABAG Association of Bay Area Governments

P. O. Box 2050
Oakland, CA 94604-2050
(415) 464-7900

MetroCenter
8th and Oak Streets
Oakland